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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to disqualify one of Plaintiffs' expert witnesses, Dr. Thomas Kinney. Doc. 5677. The motion is fully briefed, and the Court heard arguments on December 15, 2017. The Court will deny the motion.

I. Background.

Each Plaintiff in this MDL received an implant of a Bard IVC filter and claims that the filter is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of

other IVC filters, and the medical community is aware of the risks associated with IVC filters.[1]

The parties intend to use various expert witnesses at trial, including engineers, medical professionals, and regulatory experts. Dr. Kinney is a mechanical engineer, medical doctor, and interventional radiologist. Plaintiffs retained him to opine about the alleged design defects in Bard filters and Bard's alleged failure to warn physicians who implant them. Dr. Kinney and two colleagues, Drs. Anne Roberts and Sanjeeva Kalva, coauthored an expert report that, among other topics, addresses the information a physician would need to know about an IVC filter's safety and efficacy in order to conduct a proper risk-benefit analysis. *See* Doc. 5746-6 at 6-7.[2] The report also discusses clinical and testing data Bard possessed before marketing certain filters. *Id.* The report concludes in part that Bard was aware of design defects and high complication rates associated with its filters and failed to adequately warn physicians of those dangers. *Id.* at 19-29. Of the seven different versions of Bard filters at issue in this MDL, Dr. Kinney's report primarily addresses the Recovery and G2 filters.

Dr. Kinney previously served as consultant and expert witness for Bard. In June 2006, Bard retained him as an expert witness in *Mattes v. C. R. Bard, Inc.*, a district court case involving alleged perforation of the IVC caused by a Recovery filter. Eight months later, Bard retained Dr. Kinney as an expert witness in a state court case, *Ennis v. Hospital of the University of Pennsylvania*, which involved allegations that a Recovery filter had tilted and fractured. Dr. Kinney also served as an IVC filter consultant to Bard for several years beginning in 2005.

Defendants argue that Dr. Kinney must be disqualified because he has engaged in classic "side switching." Doc. 5677 at 2. Plaintiffs contend that disqualification is not

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[1] For further discussion of IVC filters and Plaintiffs' claims, see the Court's order addressing Defendants' summary judgment motion regarding preemption. Doc. 8872 at 1-6.

[2] Page citations are to numbers placed at the top of each page by the Court's electronic filing system rather than the document's original page numbers.

warranted because Dr. Kinney received no confidential information from Bard that is relevant to this MDL. Doc. 5803 at 3-14. Plaintiffs also contend that disqualification would be unfairly prejudicial. *Id.* at 13-15.

II. Disqualification Standard.

"Courts have inherent power to disqualify an expert witness to protect the integrity of the adversary process, protect privileges that otherwise may be breached, and promote public confidence in the legal system." *In re Incretin Mimetics Prods. Liab. Litig.*, MDL No. 13-md-2452 AJB, 2015 WL 1499167, at *2 (S.D. Cal. Apr. 1, 2015) (citing *Campbell Indus. v. M/V Gemini*, 619 F.2d 24, 27 (9th Cir.1980)). While the Court's power to disqualify an expert witness is clear, determining when it should be exercised can be difficult.

Courts have developed two approaches. The first, often referred to as the "bright-line rule," requires disqualification "where it is undisputed that the consultant was previously retained as an expert by the adverse party in the same litigation and had received confidential information from the adverse party pursuant to the earlier retention." *Wang Labs., Inc. v. Toshiba Corp.*, 762 F. Supp. 1246, 1248 (E.D. Va. 1991). Many cases recognize this rule. *See, e.g., In re C. R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2014 WL 6960396, at *7 (S.D. W. Va. Dec. 8, 2014); *Rhodes v. E.I. Du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 665-66 (S.D. W. Va. 2008); *Howmedica Osteonics Corp. v. Zimmer, Inc.*, No. 05-cv-0897, 2007 WL 4440173, at *2 (D.N.J. Dec. 17, 2007).

The second approach applies where "the parties dispute whether the earlier retention and passage of confidential information occurred." *Wang*, 762 F. Supp. at 1248. It includes two parts: (1) whether it was reasonable for the party seeking disqualification to believe it had a confidential relationship with the expert, and (2) whether the expert received confidential information relevant to the current litigation. *See id.*; *Bard Pelvic Repair Sys.*, 2014 WL 6960396, at *7. When both questions are answered "yes," the expert usually should be disqualified. *Id.* Before making a final

decision, however, courts consider public policy factors, including whether disqualification would be fair and promote confidence in the legal system. *See id.*; *Rhodes*, 558 F. Supp. 2d at 667-68; *Howmedica*, 2007 WL 4440173, at *2.

Some courts decline to adopt either the bright-line rule or the two-part test, but the essential factors remain the same: a confidential relationship, disclosure of confidential information, and policy considerations. *See In re Incretin Mimetics*, 2015 WL 1499167, at *3-8; *Hewlett-Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1095-96 (N.D. Cal. 2004); *Kane v. Chobani, Inc.*, No. 12-CV-02425-LHK, 2013 WL 3991107, at *5 (N.D. Cal. Aug. 2, 2013); *Auto-Kaps, LLC v. Clorox Co.*, No. 15 Civ. 1737 (BMC), 2016 WL 1122037, at *2 (E.D.N.Y. Mar. 22, 2016).

In this case, the parties address disqualification under both the bright-line rule and the two-part test. The Court will follow suit.[3]

III. Bright-Line Rule.

The parties agree that Dr. Kinney previously had a confidential relationship with Bard. The question is whether he received confidential information. For purposes of disqualification, confidential information is "information which is 'of either particular significance or that which can be readily identified as either attorney work product or within the scope of the attorney-client privilege.'" *Incretin Mimetics*, 2015 WL 1499167, at *5 (quoting *Paul*, 123 F.R.D. at 279).

Disqualification under the bright-line rule appears to be warranted only when it is undisputed that the expert received relevant confidential information. *Wang*, 762 F. Supp. at 1248; *see Theriot v. Parish of Jefferson*, No. 95-2453, 1996 WL 392149, at *2 (E.D. La. July 8, 1996) (applying bright-line rule in a "clear cut" case of side switching); *Freight Tracking Techs., LLC v. Va. Int'l Gateway, Co.*, No. 2:13cv708, 2015 WL 12602453, at *3 n.1 (E.D. Va. Feb. 11, 2015) (bright-line rule applies only to "clear

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[3] The Ninth Circuit has not adopted a specific approach, but has recognized in dicta that district courts can disqualify "an expert who is initially retained by one party, dismissed, and employed by the opposing party in the same or related litigation." *Erickson v. Newmar Corp.*, 87 F.3d 298, 300 (9th Cir. 1996).

cases" where there has been "an exchange of confidential information between an expert and one party, then the expert's retention by the opposing party in the same litigation"). Because Plaintiffs dispute whether Dr. Kinney received confidential information from Bard that relates to this MDL (Doc. 5803 at 3-13), the Court concludes that the bright-line rule does not apply.

Defendants' reliance on *Rhodes* and *Bard Pelvic Repair System* is misplaced. Each case included uncontroverted evidence that attorney work product was disclosed to the expert.

In *Rhodes*, the attorney testified that he carefully selected case-related documents for the expert to review and that those documents revealed confidential case strategy. 558 F. Supp. 2d at 669. The expert was also given a memorandum prepared by the lawyer on key legal issues. *Id.* at 771. Defendants have presented no such evidence here.

In *Bard Pelvic Repair System*, counsel for Bard testified that the expert participated in many discussions involving attorney work product in the form of mental impressions and defense strategy. 2014 WL 6960396, at *9. The attorney documented more than 75 substantive contacts with the expert, including many face-to-face meetings. *Id.* at *10. Some meetings concerned the vetting of other potential experts and strategies for cross-examining the plaintiffs' experts. *Id.* at *9-10. The expert spent more than 50 hours on the case, and testified that he understood his communications with Bard's counsel were confidential. *Id.* at 10. Disqualification was warranted under the bright-line rule because the expert "had a close working relationship with Bard's counsel, and in the course of that relationship received confidential information such as litigation strategy, mental impressions regarding strengths and weaknesses of the pelvic mesh cases, the role of experts at trial, and Bard's anticipated defenses." *Id.*

In this case, Defendants assert that their counsel shared mental impressions about the *Mattes* and *Ennis* cases with Dr. Kinney (Doc. 5677 at 7), but offer no supporting evidence. Dr. Kinney has testified that he reviewed medical records in *Mattes* and *Ennis*,

but received no attorney work product and had no discussions with counsel concerning legal issues or case strategy. Doc. 5803-1 ¶¶ 12-13.

Given this factual disagreement, Defendants have not shown that Dr. Kinney's disqualification is appropriate under the bright-line rule.

IV. Two-Part Test.

The key question under the two-part test is whether the evidence shows that Dr. Kinney received confidential information from Bard. The Court concludes that Defendants have not met their burden of making this showing.[4]

Dr. Kinney served as a paid consultant to Bard between 2005 and 2008. To facilitate this work, the parties entered into several agreements, each of which contemplated the disclosure of confidential information. The first was a "Confidential Information Agreement" in which the Bard agreed to disclose confidential information relating to IVC filters. Docs. 5747, 5803-1 ¶ 7. In others, Dr. Kinney acknowledged that he would receive confidential information in connection with the performance of his consulting services. For example, in the August 8, 2007 agreement, Dr. Kinney, who was referred to as "Provider," gave this express acknowledgment: "Provider acknowledges that confidential or proprietary information or materials, including but not limited to the Protocol, will be made available to Provider or developed by Provider in connection with performance of the Services[.]" Doc. 5747-5, ¶ 8. Other agreements contain similar acknowledgements. *See, e.g.*, Doc. 5679-2, ¶ 8. Dr. Kinney was also involved in three animal studies for Bard, and the agreement for each contained a provision concerning confidential information. Docs. 5747-1 ¶ 5, 5747-3 ¶ 5, 5747-4 ¶ 8. And as noted above, he was retained as an expert witness in two Bard cases.

[4] The *Rhodes* court stated that the second element of the two-part test is satisfied if "the expert received *or had reasonable access to*" confidential information. 558 F. Supp. 2d at 667 (emphasis added). But *Rhodes* does not discuss disqualification based solely on "reasonable access" to confidential information, and the Court has not seen it addressed in other cases. The Court therefore concludes that the two-part test is satisfied only if the expert actually received confidential information.

It appears likely from these agreements and retentions that Dr. Kinney actually received confidential information. But likelihood is not enough. Defendants must present evidence that confidential information was in fact conveyed. In a recent unpublished decision, the Ninth Circuit noted that such evidence must be "specific and unambiguous." *In re: Incretin-Based Therapies Products Liability Litigation*, No. 15-56997, 2017 WL 6030735, at *3 (9th Cir. Dec. 6, 2017) (citing *Hewlett-Packard*, 330 F. Supp. 2d at 1094).

Defendants have not produced specific and unambiguous evidence that Dr. Kinney received confidential information. They claim in their briefing that he received such information from various attorneys – attorneys who are still involved in this litigation – but they provide no declarations from those attorneys concerning information they shared with Dr. Kinney. Nor do Defendants provide evidence from any other Bard employee regarding such information. Indeed, aside from providing very general descriptions, Defendants make no effort to identify the confidential information Dr. Kinney received or the parts of his expert report that are based on Bard confidences. If Defendants were concerned about publicly disclosing the very information they seek to protect, they could have proposed an *in camera* submission, but they have not done so.

Dr. Kinney, by contrast, avows that he never received confidential information from Bard. Doc. 5803-1. Although the Court might be inclined to view this evidence as self-serving in light of the extensiveness of his prior relationship and the number of confidentiality provisions he executed, Dr. Kinney's declaration is uncontroverted. Defendants present no declarations of their own.

Disqualification is a drastic measure, to be used sparingly. *Hewlett-Packard*, 330 F. Supp. 2d at 1092. "Cases granting disqualification are rare because courts are generally reluctant to disqualify expert witnesses, especially those . . . who possess useful specialized knowledge." *Rhodes*, 558 F. Supp. 2d at 664 (quotation marks and citations omitted). "Accordingly, the party seeking disqualification bears a 'high standard

of proof' to show that disqualification is warranted." *Id*. (citations omitted). Defendants have not met this high standard of proof with respect to Dr. Kinney.

IT IS ORDERED:

1. Defendants' motion to disqualify Thomas Kinney, M.D. as an expert for Plaintiffs (Doc. 5677) is **denied**.
2. Plaintiffs' motion for leave to file a surreply (Doc. 6682) is **granted**. The Clerk is directed to file the lodged surreply (Doc. 6683).

Dated this 21st day of December, 2017.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to disqualify four medical experts: Drs. Scott Resnick, Robert Vogelzang, Kush Desai, and Robert Lewandowski. Doc. 6678. The motion is fully briefed, and the Court heard oral arguments on December 15, 2017. The motion is moot with respect to Dr. Resnick, and will be denied for the other doctors.

I. Background.

Each Plaintiff in this MDL received an implant of a Bard IVC filter and claims that the filter is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer

fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters, and the medical community is aware of the risks associated with IVC filters.

The parties intend to use various expert witnesses at trial, including medical professionals. The doctors subject to the present motion are colleagues at Northwestern University's interventional radiology department. The doctors formed a consulting group, SBBK Consultants, LLC ("SBBK"), for purposes of IVC filter litigation. Plaintiffs retained SBBK in this MDL, and Drs. Vogelzang and Desai have provided three expert reports concerning medical problems caused by alleged defects in Bard IVC filters. Plaintiffs have listed Drs. Vogelzang and Desai as testifying experts.[1]

Defendants seek to disqualify each doctor, and SBBK as a whole, because Dr. Resnick served as a consultant to Bard and previously worked for Bard as an expert in IVC filter litigation. Doc. 6678. Given this prior relationship and Dr. Resnick's involvement in drafting the expert reports, Defendants contend that each SBBK expert effectively has engaged in impermissible "side switching." *Id.* at 8.[2]

Plaintiffs do not oppose Dr. Resnick's disqualification. They contend, however, that his colleagues should not be disqualified because they had no confidential relationship with Bard and received no Bard confidential information from Dr. Resnick. Doc. 7029 at 1-3 & n.2. Plaintiffs further contend that disqualification of Drs. Vogelzang and Desai as testifying experts would be unfair. *Id.* at 12-14.

II. Disqualification Standard.

"Courts have inherent power to disqualify an expert witness to protect the integrity of the adversary process, protect privileges that otherwise may be breached, and promote public confidence in the legal system." *In re Incretin Mimetics Prods. Liab. Litig.*, MDL

[1] Drs. Resnick and Lewandowski participated in drafting the expert reports, but Plaintiffs do not intend to use them as testifying experts.

[2] Page citations are to numbers placed at the top of each page by the Court's electronic filing system rather than the document's original page numbers.

No. 13-md-2452 AJB, 2015 WL 1499167, at *2 (S.D. Cal. Apr. 1, 2015) (citing *Campbell Indus. v. M/V Gemini*, 619 F.2d 24, 27 (9th Cir.1980)). Courts have developed two tests for the exercise of this power, a bright-line rule and a two-part test.

The bright-line rule applies where it is undisputed that the expert was retained by, and received confidential information from, one party and then switched sides in the same litigation. *Wang Labs., Inc. v. Toshiba Corp.*, 762 F. Supp. 1246, 1248 (E.D. Va. 1991). Where the parties disagree on whether the expert had a confidential relationship or received confidential information, courts apply a two-part test that asks whether the party seeking disqualification has shown (1) it was reasonable for the party to believe that a confidential relationship existed, and (2) the expert received or had reasonable access to confidential information relevant to the current litigation. *Id.*; *see In re C. R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2014 WL 6960396, at *7 (S.D. W. Va. Dec. 8, 2014). Courts also consider public policy factors, including whether disqualification would be fair and promote confidence in the legal system. *Wang*, 762 F. Supp. at 1248; *Rhodes v. E.I. Du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 667-68 (S.D. W. Va. 2008).[3]

III. Dr. Resnick.

Plaintiffs' response to Defendants' motion includes this statement:

> Plaintiffs' Counsel did not know of Dr. Resnick's past relationship consulting with Bard when they hired him as a non-testifying consultant, and since learning of such, as a result of Bard's motion (July 12, 2017), Plaintiffs' Counsel represents that he has instructed Doctors Vogelzang and Desai not to consult in any manner with Dr. Resnick on this case going forward, and they have agreed and complied. Thus, Dr. Resnick will not have any future role in this case, and that aspect of the motion is moot.

Doc. 7029 at 2. In light of this avowal, the Court concludes that the motion is moot with respect to Dr. Resnick.

[3] The Ninth Circuit has not adopted a specific approach, but has recognized in dicta that district courts can disqualify "an expert who is initially retained by one party, dismissed, and employed by the opposing party in the same or related litigation." *Erickson v. Newmar Corp.*, 87 F.3d 298, 300 (9th Cir. 1996).

IV. Drs. Vogelzang and Desai and Their Expert Reports.

Drs. Vogelzang and Desai have provided three expert reports. Plaintiffs argue that the doctors should not be disqualified as testifying experts under either the bright-line rule or the two-part test because they had no confidential relationship with Bard and received no confidential Bard information. Doc. 7029 at 2-3. Plaintiffs contend that no information Bard provided to Dr. Resnick had any influence on the reports and opinions of his colleagues. *Id.* at 9; *see* Docs. 7029-1, 7029-2 ¶ 4.

Defendants do not claim that Drs. Vogelzang and Desai had confidential relationships with Bard, nor that they personally received confidential information from Bard. As a result, neither doctor would be disqualified under a traditional application of the bright-line rule or the two-part test. Defendants' argument is based on the fact that Dr. Resnick worked with Drs. Vogelzang and Desai in the creation of their expert reports. Defendants argue that the sharing of confidential information in such a setting is unavoidable, and that any claim to the contrary "does not seem credible." Doc. 7058 at 4. Defendants also argue that the entity SBBK, which includes Drs. Vogelzang and Desai, should be disqualified from this litigation. *Id.* (citing *Kane v. Chobani, Inc.*, No. 12-CV-02425-LHK, 2013 WL 3991107, at *5 (N.D. Cal. Aug. 2, 2013)).

The Court concludes that disqualification would be warranted in this circumstance only if Defendants presented evidence that Drs. Vogelzang and Desai actually received Bard confidences. Disqualification is a drastic measure that should be used sparingly. *Hewlett-Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1092 (N.D. Cal. 2004). "Cases granting disqualification are rare because courts are generally reluctant to disqualify expert witnesses, especially those . . . who possess useful specialized knowledge." *Rhodes*, 558 F. Supp. 2d at 664 (quotation marks and citations omitted). "Accordingly, the party seeking disqualification bears a 'high standard of proof' to show that disqualification is warranted." *Id.* (quotation marks and citations omitted).

Defendants have not satisfied this high standard. Drs. Vogelzang, Desai, and Resnick have provided sworn declarations stating that Dr. Resnick never shared

confidential Bard information with the other doctors. Docs. 7029-1, 7029-2, 7029-3. Defendants provide no evidence to the contrary. Defendants offer no declaration concerning the nature or extent of the confidential information shared with Dr. Resnick. They deposed Drs. Vogelzang and Desai after they knew of their collaboration with Dr. Resnick, and yet never asked them about their communications with Dr. Resnick or the sharing of any Bard-related information. Defendants make no effort to identify Bard confidential information found in the expert reports of the doctors. And although Defendants complain that such efforts would require them to reveal the very confidences they seek to protect, Defendants are well aware of *in camera* procedures and have made no request to submit confidential information to the Court that would identify the confidences that have been compromised.

In short, Defendants ask the Court to disqualify Drs. Vogelzang and Resnick on the *assumption* that they received confidential Bard information from Dr. Resnick. The Court concludes that the drastic step of expert disqualification cannot be based on an assumption. *See Williams v. Old Faithful Tours, Inc.*, No. 11-CV-287-F, 2012 WL 9490902, at *4 (D. Wy. Sept. 25, 2012) (denying motion to disqualify where the expert affirmed under oath that he neither received nor used any confidential information provided by the adverse party in developing his report); *Sarl v. Sprint Nextel Corp.*, No. 09-2269-CM/DJW, 2013 WL 501783, at *7 (D. Kan. Feb. 8, 2013) (requiring receipt of confidential information concerning legal strategies to warrant disqualification where the expert had no prior relationship with the moving party); *In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 15-56997, 2017 WL 6030735, at *3 (9th Cir. Dec. 6, 2017) (suggesting that disqualification of an expert should not occur unless the court has "specific and unambiguous" evidence that the expert received confidential information).[4]

[4] In order to protect the highly sensitive attorney-client relationship, attorney disqualification rules permit courts to assume that confidences were received. *See Trone v. Smith*, 621 F.2d 994, 999 (9th Cir. 1980) ("As we have stated, the underlying concern is the possibility, or appearance of the possibility, that the attorney may have received confidential information during the prior representation that would be relevant to the subsequent matter in which disqualification is sought. The test does not require the former client to show that actual confidences were disclosed."). But expert

Disqualification of Drs. Vogelzang and Desai would also seriously prejudice Plaintiffs at this late stage of the litigation. Discovery has closed, expert motions have been filed, and the parties are preparing to begin bellwether trials. Disqualifying Drs. Vogelzang and Desai now would mean that Plaintiffs must proceed without their area of expertise, something the Court is not willing to require in the absence of evidence that Defendants have been disadvantaged in some way. *See Williams*, 2012 WL 9490902, at *4 (declining to disqualify expert because doing so would leave the proponent of his testimony "scrambling to find a liability expert on the eve of trial").[5]

Defendants' reliance on *Kane v. Chobani*, 2013 WL 3991107, at *5, is misplaced. The court in that case was presented with sworn declarations from defense counsel that they discussed litigation strategy with the consulting group and a particular consultant who switched sides. *Id.* at *6. Defendants have presented no such evidence in this case. Moreover, the court in *Kane* found no prejudice from disqualification because the case was still in its initial stages. *Id.* at *7.

IT IS ORDERED that Defendants' motion to disqualify experts (Doc. 6678) is moot with respect to Dr. Resnick and is otherwise **denied**. The Court enters this order in reliance on Plaintiffs' avowal that Dr. Resnick will have no further involvement in this case.

Dated this 21st day of December, 2017.

David G. Campbell
United States District Judge

disqualification cases have declined to adopt such an approach. *See, e.g., Hewlett-Packard Co.*, 330 F. Supp. 2d at 1092; *U.S. ex rel. Cherry Hill Convalescent, Ctr., Inc. v. Healthcare Rehab Sys., Inc.*, 994 F. Supp. 244, 249 (D.N.J. 1997); *Formosa Plastics Corp. v. Kajima Int'l, Inc.*, 216 S.W.3d 436, 451 (Tex. Ct. App. 2006).

[5] The fourth member of SBBK, Dr. Lewandowski, has no prior relationship with Bard and is not a testifying expert in this case. The Court therefore also concludes that his disqualification is unnecessary.

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FOR THE DISTRICT OF ARIZONA

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This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed motions to exclude the opinions of two regulatory experts, Drs. Suzanne Parisian and David Kessler. Docs. 7308, 7309. The motions are fully briefed, and the Court heard arguments on December 15, 2017. The Court will grant the motions in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. Each filter received premarket clearance from the Food and Drug Administration ("FDA").[1]

[1] For further discussion of IVC filters and the FDA regulatory process, see the Court's order addressing Defendants' summary judgment motion regarding preemption. Doc. 8872 at 2-5.

Each Plaintiff in this MDL received an implant of a Bard IVC filter and claims that the filter is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1.

Bard disputes Plaintiffs' allegations, contending that complication rates for Bard filters are comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters. Bard contends that the FDA's premarket clearance of its IVC filters and labels shows that the filters are safe and effective, and that Bard provided adequate warnings to implanting physicians.

The parties intend to use various expert witnesses at trial, including engineers, medical professionals, and regulatory experts. Plaintiffs have identified Drs. Parisian and Kessler as FDA regulatory experts. Dr. Parisian is a board-certified pathologist with a master's degree in biology. She served as an FDA medical officer in the early 1990s. Dr. Kessler is a former FDA Commissioner who holds a medical degree from Harvard Medical School and a law degree from the University of Chicago Law School. He is a professor of food and drug law, and serves as an advisor to pharmaceutical and biomedical companies.

Defendants agree that Drs. Parisian and Kessler are qualified, based on their knowledge, experience, and training, to serve as experts regarding the FDA regulatory process for medical devices. Defendants also agree that the FDA process is complex and beyond the experience of the average juror, and that opinions of regulatory experts therefore may prove helpful to the jury. Defendants argue, however, that the specific opinions and proposed testimony of Drs. Parisian and Kessler are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

II. Legal Standard.

Under Rule 702, an expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). The proponent of expert testimony has the ultimate burden of showing, by a preponderance of the evidence, that the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). But the trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not solely to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Dr. Parisian.

Dr. Parisian presents a difficult challenge. Her report is 257 pages long, unwieldy, often unfocused, and poorly organized. As another court aptly observed, "Dr. Parisian's report is a labyrinth that the Court cannot navigate." *Lopez v. I-Flow Inc.*, CV 08-1063-PHX-SRB, 2011 WL 1897548, at *10 (D. Ariz. Jan. 26, 2011). Numerous courts have excluded her FDA-related testimony because she fails to identify a clear methodology, engages in lengthy factual narratives, opines on subjects well outside her area of expertise, and often acts more as an advocate than an expert.

And yet Dr. Parisian appears to have FDA expertise, and some of her opinions are relevant to this case. Because it is not possible to address everything in her expert report, the Court is forced to paint with broad strokes.

A. Difficulties Presented by Dr. Parisian's Report.

Dr. Parisian's report lists hundreds of documents, deposition transcripts, and expert reports she reviewed in preparing her opinions. Doc. 7312 ¶¶ 10-14. Dr. Parisian provides an overview of the FDA's 510(k) clearance process in general and as it relates

to IVC filters. *Id.* ¶¶ 17-76. Then, over the next 200 or so pages, she states the following opinions:

- Opinion 1: Bard's premarket actions with design and development of the Recovery filter as a permanent filter were inadequate (¶¶ 77-210);
- Opinion 2: Bard obtained FDA clearance to market the Recovery filter as both a permanent and retrievable IVC filter yet failed to provide physicians and patients with adequate warnings (¶¶ 211-346);
- Opinion 3: Bard's actions for post-market oversight continued to permit marketing of the flawed Recovery filter (¶¶ 347-456);
- Opinion 4: Bard developed its "next generation" of IVC filters based on piecemeal reactive modifications to its flawed Recovery filter platform rather than use of quality science and design principles (¶¶ 457-651);
- Opinion 5: Bard's quality systems and post market monitoring procedures were flawed, helped underestimate risk, and permitted continued commercial release of misbranded and dangerous products as supported by Bard's receipt of an FDA 2015 warning letter (¶¶ 652-673);
- Opinion 6: Bard engaged in aggressive off-label promotions which overstated benefits, downplayed risks, expanded the implanted patient population, and failed to adequately warn physicians, patients, and its own sales force of the risks (¶¶ 674-742);
- Opinion 7: Bard marketed the Recovery Cone Retrieval System as part of the Recovery IVC filter system to facilitate filter retrieval without having obtained 510(k) clearance (¶¶ 743-758).[2]

Each of these opinions is followed by a string cite of various FDA regulations, without explanation, and by a lengthy discussion of documents, depositions, events, and other facts regarding alleged flaws in Bard IVC filters, what Bard knew or should have known about those flaws, and what Bard failed to disclose to the FDA and the medical community. Doc. 7312 at 37-255. Dr. Parisian largely fails to explain how her factual recitations relate to or support her opinions. Nor does she explain how the facts relate to

[2] Dr. Parisian submitted a fifty page supplemental report that offers six of these opinions with regard to the Meridian and Denali filters. Doc. 7312-1.

her string cites of regulations. On the rare occasion where she states that Bard violated a specific regulation with some specific action, she fails to explain why that regulation was violated. *See* Doc. 7312 ¶¶ 343, 665.

Other courts have encountered similar problems with Dr. Parisian's opinions. In *Trasylol*, the court found that "[a]ll of Dr. Parisian's opinions suffer from this fatal flaw: she recounts [the] regulatory history, the contents of [defendants'] internal documents and e-mails, and the findings of scientific studies; she then offers a broad opinion, often outside her scope of expertise, that is not connected to the underlying facts in any apparent way and that lacks regulatory analysis." *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1347 (S.D. Fla. 2010); *see also Lopez*, 2011 WL 1897548, at *10 ("Dr. Parisian's report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation"); *Miller v. Stryker Instruments*, No. CV-09-813-PHX-SRB, 2012 WL 1718825, at *11 (D. Ariz. Mar. 29, 2012) (Dr. Parisian provides "no analysis or explanation of [her] conclusory opinion" that the defendant violated FDA regulations); *Kaufman v. Pfizer Pharm., Inc.*, No. 1:02-CV-22692, 2011 WL 7659333, at *9 (S.D. Fla. Aug. 4, 2011) ("Dr. Parisian generally takes a collection of facts, imputes [defendants'] motive and knowledge to those facts, and draws unsupported conclusions that are unrelated to any regulatory experience that she has"); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (Dr. Parisian's testimony is "riddled with conclusory statements lacking either analysis or explanation; improperly touches on issues well beyond [her] qualifications; and at times, merely regurgitates factual information that is better presented directly to the jury"); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. July 8, 2008) (Dr. Parisian "testified to the bottom line without any explanation, failed to provide expert analysis, . . . testified in areas beyond her expertise, and invaded areas that required no expert testimony"); *Jacob v. Ceasars Entm't, Inc.*, No. 05-0805, 2007 WL 594714, at *4 (E.D. La. Feb. 21, 2007) ("Although [Dr. Parisian is] qualified by education, training and experience to render

opinions, [her] opinions are not based on sufficient facts or data, and the methodology used by [her] is unreliable").

B. The Parties' Positions.

Defendants argue that Dr. Parisian's testimony should be excluded entirely. They assert that she is an advocate, not an expert; she improperly opines on filter design and testing and on issues of medical causation; she provides testimony outside the scope of proper expert opinions, including factual narratives, legal conclusions, and speculation on Bard's intentions and ethics; and her opinions lack a coherent methodology. Doc. 7814.

Plaintiffs state that they intend to use Dr. Parisian to provide testimony on several specific subjects: (1) the role, procedure, and function of the FDA in its oversight of medical device manufacturers; (2) the duties and responsibilities of Bard to obtain FDA clearance for its IVC filters and to market safe and effective devices; (3) the duties and responsibilities Bard has under FDA rules to protect consumers of its products by monitoring device performance and communicating the risks attendant to the use of its devices to the public and physicians; (4) the process by which manufacturers apply for, document, and obtain regulatory clearance for devices such as IVC filters; (5) Bard's continuing duty to maintain expertise about its product and investigate risks related to its product; (6) the adequacy of Bard's pre- and post-market study, design, testing, validation, and monitoring of its retrievable IVC filters, starting with the Recovery filter; and (7) Bard's specific failures to comply with its duties under FDA regulations. Doc. 7184 at 6-7.

Unfortunately, Plaintiffs' description of these opinions bears little resemblance to Dr. Parisian's report. Her report ventures far beyond these subjects. As only a few examples, Dr. Parisian frequently states opinions on Bard's intentions and motivations, as though she were an expert on corporate psychology or strategy and internal Bard philosophies. She opines, for example, that Bard made IVC changes "in a piecemeal and reactive fashion heaped onto a flawed underlying [Recovery filter] platform with a goal to address physician perceptions about improvement to the prior generation of product.

. . . Bard's evolution of changes starting with the [Recovery filter] were not primarily made to improve quality, safety, and efficacy, or to protect patients but rather primarily to address sales force and physician perceptions about device problems and help keep and expand market share." Doc. 7312 at 162. She thus opines on *why* Bard took particular actions, a subject clearly not within her FDA expertise. Dr. Parisian also freely opines on Bard's intention in renaming some of its filters, asserting that it was done to "address lukewarm sales and waning physician support." *Id.* at 207. She offers opinions on the nature and sufficiency of corrosion testing, a matter well beyond her expertise. *Id.* at 218. These kinds of opinions are sprinkled through pages of factual narrative that often read more like a lawyer's closing argument than an expert's considered opinion. As noted in the case parentheticals set forth above, many courts have encountered this tendency on the part of Dr. Parisian, and many have excluded her testimony because of it.

Apparently aware that her report ventures beyond proper expert testimony, Plaintiffs set forth several concessions in their response to Defendants' motion. These include the following:

- Dr. Parisian "is not being proffered to testify in a narrative form[,]" and "the factual materials considered . . . are not intended to be the subject of her testimony in and of themselves." Doc. 7814 at 12, 16.
- Dr. Parisian "will not express any opinions on Bard's intent, motives, or state of mind." *Id.* at 12.
- "Dr. Parisian is not an engineer and cannot testify as to alternative designs or design defects in Bard's IVC filters." *Id.* at 14.
- Dr. Parisian "is not a medical specialist in areas relevant to causation issues in this case, such as interventional radiologist, cardiologist, internal medicine doctor, or hematologist. Plaintiffs thus concede that, to the extent that any opinion offered by Dr. Parisian at trial could be reasonably construed as being an opinion only on . . . 'causation' that Dr. Parisian will not offer such testimony." *Id.*

What, then, should the Court do with an overly broad and unwieldy report that in large respects is inconsistent with Plaintiff's description of how they intend to use Dr. Parisian at trial? It is not possible for the Court to parse her 257-page report, identifying which opinions are admissible and which are not, nor have the parties provided arguments that would enable the Court to do so. Faced with this difficulty, the best the Court can do is identify general areas within which Dr. Parisian will be permitted to testify and the general restrictions that will be placed on her at trial. More precise line-drawing must occur during trial.

C. The Court's Rulings on Dr. Parisian.

1. Plaintiffs' Concessions.

The Court accepts and agrees with each of Plaintiffs' concessions set forth in the bullet points above. Dr. Parisian will not be allowed to present a factual narrative at trial; to express opinions on Bard's intent, motives, or state of mind; to testify on alternative designs or design defects; or to testify on medical causation issues. Nor will she be permitted to testify on manufacturing or testing defects in Bard processes or about expectations or practices of physicians and patients with which she is not personally familiar. Dr. Parisian is not qualified by training or experience to testify on these matters as required by Rule 702.

2. Permitted Areas of Testimony.

Dr. Parisian will be permitted to testify about FDA practices and the 510(k) process as set forth at the beginning of her expert report. *See* Doc. 7312 at 21-36. Instruction on relevant matters beyond the understanding of a typical juror is an appropriate function of an expert witness. *EEOC v. S&B Indus., Inc.*, No. 3:15-CV-0641-D, 2017 WL 345641, at *4 (N.D. Tex. Jan. 24, 2017) ("If an expert distills a complicated subject into language a jury can understand, and that subject is relevant, she can be admitted as a 'teaching witness.'"). Dr. Parisian will also be permitted to testify regarding Bard's participation in the 510(k) process and its compliance with that process. *See In re C. R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, 948 F. Supp. 2d 589, 629

(S.D. W. Va. 2013) (allowing regulatory expert to offer testimony regarding "the FDA 510(k) framework and process [and] Bard's actions taken with respect to this framework and process"); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 481-82 (S.D.N.Y. 2016) ("Dr. Parisian's testimony regarding the complex FDA regulatory framework [and the defendant's] compliance with FDA regulations . . . [is] relevant to this case and would be helpful to the jury."). Although it is difficult to draw precise lines, Dr. Parisian generally will be permitted to testify on the seven specific subjects identified in Plaintiffs' response, as quoted above (Doc. 7184 at 6-7), provided those opinions are disclosed in her expert report or deposition. *See* Case Management Order No. 8, Doc. 519, ¶ (I)(B).

3. Dr. Parisian's Methodology.

Defendants assert that Dr. Parisian has failed to identify the methodology used to arrive at her opinions. Rule 702 requires that expert testimony be "the product of reliable principles and methods." Fed. R. Evid. 702(c). Dr. Parisian describes her methodology as follows:

> I have used the same methodology I was trained to use at the FDA to reach the opinions discussed in this report regarding the design, development, and promotion of "retrievable" [Bard IVC filters]. I have continuously used this same methodology since 1991. This process included analyses of Bard's communications with the FDA during the 510(k) clearance process, as well as Bard's internal product development documents for both Bard's retrievable IVC filters and the Simon Nitinol Filter permanent IVC filter, which Bard asserted was also the predicate for its temporary IVC filters. My review included Bard's postmarket investigation of adverse events, manufacturing and design issues with its commercial permanent and retrievable filters, and its communications of risks and benefits to its sales force, physicians, key opinion leaders, the FDA, and patients.

Doc. 7312 ¶ 9.

To summarize this description, Dr. Parisian conducted "analysis" and "review" of various communications and documents. Although this description of methodology clearly is insufficient, it makes more sense when read in light of Dr. Parisian's

qualifications and her description of the 501(k) process. Dr. Parisian states that during her time at the FDA (1991 to 1995) she was primarily assigned to the Center for Devices and Radiological Health ("CDRH"). *Id.* at 9, ¶ 1. She also provided regulatory support to the FDA's Office of Compliance and Office of Device Evaluation ("ODE"). *Id.* at 9, ¶ 2. She was responsible for reviewing "adverse event reports and medical literature, and review of product labeling, promotions, advertising, and corporate records as to compliance with the Food, Drug and Cosmetic Act." *Id*. Her assignment "specifically included identification and mitigation of safety issues for the public." *Id*. Her report explains that the CDRH has a role in reviewing product modifications of already cleared devices, changing market claims, addressing safety and performance issues, or helping clear a new generation of devices or technologies. *Id.* at 21, ¶ 18. The ODE's role is pre-market clearance, which was the process by which Bard filters were cleared for sale. *Id*.

When Dr. Parisian's role in these FDA processes are understood, her methodology makes more sense. She appears to be saying that she engaged in the same kind of fact and document analysis in this case that she used when assigned to CDHR and when she provided regulatory support for ODE. Thus, it appears that Dr. Parisian is looking at relevant information from the eyes of an FDA regulator. This certainly is an area of specialized experience or training, and it could be helpful to the jury in understanding the FDA-related evidence that will be presented at trial and the significance of FDA's clearance of Bard's filters. *See Bard Pelvic Repair Sys.*, 948 F. Supp. 2d at 629. If done in a manner consistent with FDA practices, it could constitute a reliable method for rendering opinions as required by Rule 702(c). Thus, although Dr. Parisian's description of her methodology could be clearer, the Court concludes from her report as a whole that her methodology is sufficient to support opinions on FDA procedures and practices and Bard's compliance with those procedures and practices. *See Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013) ("[T]he Court finds that Dr. Parisian's opinions are supported by a sufficiently reliable methodology. She has grounded her opinions in sources including Woo Young's internal documents, pertinent scientific

literature, and publicly available documents, as well as her expertise."); *Fosamax v. Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) ("Dr. Parisian has drawn conclusions about Merck's conduct based on her review of pertinent portions of the regulatory filings for Fosamax and Merck's internal company documents. This is the methodology she applied as a Medical Officer[.]").

4. Legal Conclusions.

The Ninth Circuit "has repeatedly affirmed that 'an expert witness cannot give an opinion as to her *legal conclusion*, i.e., an opinion on an ultimate issue of law.'" *United States v. Diaz*, --- F.3d ----, 2017 WL 6030724, at *2 (9th Cir. Dec. 6, 2017) (citations omitted; emphasis in original). "This prohibition of opinion testimony on an ultimate issue of law recognizes that, 'when an expert undertakes to tell the jury what result to reach, this does not *aid* the jury in making a decision, but rather attempts to substitute the expert's judgment for the jury's.'" *Id.* Given this prohibition, Dr. Parisian will not be permitted to provide legal conclusions concerning Plaintiffs' state law tort claims. For example, she will not be allowed to opine that Bard failed to adequately warn physicians of risks associated with Bard filters. *See* Doc. 7312 at 125, 241.

That is not to say, however, that Dr. Parisian and other qualified regulatory experts are precluded from offering opinions related to FDA procedures. Because FDA procedures are beyond the ken of average jurors, it will be helpful to have Dr. Parisian, or another qualified regulatory expert, describe how the 510(k) process works, how a manufacturer navigates the process, and how the FDA renders a decision based on the process. *See In re Yasmin & YAZ Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 6302287, at *12 (S.D. Ill. Dec. 16, 2011) ("Dr. Parisian's testimony is permissible because of the complex nature of the [FDA] process and procedures and the jury needs assistance understanding it."). This description necessarily will entail a discussion of relevant FDA regulations and the legal requirements they may impose on manufacturers. This Circuit has noted that "it is sometimes impossible for an expert to render his or her opinion on a subject without resorting to language that recurs in the applicable legal

standard." *Diaz*, 2017 WL 6030724, at *3.

It also may be appropriate for a regulatory expert to opine as to what the FDA did in this case, and whether the FDA would have cleared a particular filter or label had certain facts been disclosed. Dr. Parisian's testimony in this regard may be relevant and necessary for Plaintiffs to rebut Defendants likely assertion that they are not liable because they complied with FDA procedures and ultimately received clearance for each filter and label.[3]

5. Preemption.

Defendants contend that Dr. Parisian's opinions regarding regulatory compliance are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Doc. 7308 at 12-13. But *Buckman* is a "claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preemption case." *Yasmin*, 2011 WL 6302287, at *11. Plaintiffs have made no claim of fraud on the FDA, and, with one possible exception, Plaintiffs' state law tort claims do not exist solely by virtue of the FDCA. *See* Doc. 303-1 ¶¶ 166-338.[4] The Supreme Court has made clear that federal law does not prevent juries in failure to warn cases from considering a manufacturer's compliance with FDA regulations. *Wyeth v. Levine*, 555 U.S. 555, 569-73 (2009). In short, evidence of regulatory compliance in this case is not preempted. *See In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 15-56997, 2017 WL 6030735, at *2 (9th Cir. Dec. 6, 2017) ("Neither *Buckman*'s holding nor what the district court termed the 'policy underlying *Buckman*' can be read to preclude the discovery of evidence relevant to the plaintiffs' state-law failure to warn claims.") (citing *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc)); *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040-41 (9th Cir.

[3] Plaintiffs apparently intend to argue that the Court should preclude Defendants from presenting FDA evidence and making such arguments. If the Court limits Defendants' FDA evidence, it likely will also limit Plaintiffs' FDA evidence. That is a matter that must be addressed at trial.

[4] The Court granted summary judgment on the negligence per se claim asserted in the Booker case because no violation of any state statute was alleged and the claim therefore relied solely on the FDCA and ran afoul of 21 U.S.C. § 337(a). Doc. 8874 at 14-17.

2015) (rejecting the defendant's preemption argument and proposition that "any use of federal law to establish a standard of care is an attempt to enforce the underlying federal provisions"); *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565, 587 (E.D. La. 2005) (*Buckman* does "not bar a qualified expert from testifying as to their opinion on whether the FDA correctly balanced the benefits and risks of a drug from a regulatory standpoint").

6. Control of Dr. Parisian at Trial.

Defendants' concerns about Dr. Parisian's tendency to provide lengthy factual narratives, argumentative testimony, and opinions beyond her area of expertise appear to be well founded. Dr. Parisian will not be allowed to engage in such practices at trial. Upon appropriate objections or to avoid clear error, the Court will limit her testimony to opinions within the area of her FDA expertise, terminate extended narratives, strike argumentative answers, and not permit unfounded opinions or ultimate legal conclusions. Plaintiffs' counsel should prepare Dr. Parisian to stay with the bounds of her expertise and to avoid unwarranted narrative or argumentative answers.

So limited, the Court concludes that Dr. Parisian's FDA expertise and opinions satisfy Rule 702. The Court will grant in part and deny in part Defendants' motion. The motion is granted with respect to the areas identified above in paragraph (C)(1). The motion is denied with respect to testimony within her area of FDA expertise. More precise decisions will be made at trial.

IV. Dr. Kessler.

As a medical doctor, professor of food and drug law, and former FDA Commissioner, Dr. Kessler is qualified to opine on regulatory issues that relate to Bard IVC filters. *See In re Xarelto Prods. Liab. Litig.*, MDL No. 2592, 2017 WL 1352860, at *2-3 (E.D. La. Apr. 13, 2017) (discussing Dr. Kessler's qualifications). In his expert reports, Dr. Kessler describes how Bard obtained premarket clearance for its Recovery and G2 filters under the 510(k) process, and explains that this process requires a showing of substantial equivalence to a predicate device and not independent proof of safety and

effectiveness. Generally speaking, Dr. Kessler offers the following opinions about Bard's filters and regulatory conduct: Bard failed to comply with FDA regulations, disclose adverse information to the FDA, and otherwise assure the safety and effectiveness of the Recovery and G2 filters; Bard filters present unacceptable risks to patients; Bard made misleading statements about the design and performance of its filters; the FDA would not have cleared the Recovery filter had Bard provided adequate disclosures; Bard failed to remove the Recovery filter from the market despite its increased risks; Bard failed to adequately warn physicians and patients about known filter complications; and Bard's strategy to design filters to be retrievable, but market them for permanent use, put patients at risk. Doc. 7313.

Defendants' primary challenge to Dr. Kessler's opinions is that he offers improper legal conclusions. Doc. 7309 at 3-7. Defendants also object to his factual narratives and his opinions about what the FDA would have done with allegedly withheld information; IVC filter design, testing, and causation; and Bard's intent and ethics. *Id.* at 7-13. The Court will address each argument in turn.

A. Legal Conclusions.

As explained above, an expert witness may not opine on an ultimate issue of law. *See Diaz*, 2017 WL 6030724, at *2. Thus, Dr. Kessler will not be permitted to provide ultimate legal conclusions concerning Plaintiffs' state law tort claims. *See Bard Pelvic Repair Sys.*, 948 F. Supp. 2d at 629 ("The questions of whether Bard's . . . products were not reasonably safe, . . . or whether Bard failed to warn, are questions for the jury, not Dr. Kessler."). Dr. Kessler may, however, offer opinions concerning the FDA regulatory process and Bard's compliance with the process. *See Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221, at *1 (W.D. Okla. Feb. 4, 2013) ("Dr. Kessler may *not* testify as to the elements of a strict liability or negligence claim under Oklahoma law but *may* testify as to the law governing FDA regulations.") (emphasis in original); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14-C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) ("[The] plaintiffs' claims are based on state law

doctrines such as negligence, failure to warn, strict products liability, breach of warranty, and fraud. The ultimate conclusions a jury will have to draw are rooted in state law, not federal law. And Dr. Kessler's testimony does not cover the ultimate issues that the jury will decide; rather, it concerns . . . FDA regulations. This is neither irrelevant [nor] improper[.]"). Plaintiffs avow that Dr. Kessler is well aware of his limited role as an expert on FDA regulatory matters and will not offer impermissible legal conclusions or instruct the jury on the law. Doc. 7805 at 11-13. The Court will hold Plaintiffs to their word, and is confident Defendants will object if Dr. Kessler crosses the line into inadmissible legal conclusions.

Defendants contend that given Dr. Kessler's impressive credentials, Plaintiffs will present him to the jury as the ultimate authority on FDA matters. Doc. 7309 at 2-3. One court recently noted that this argument seems to be that Dr. Kessler is *too* qualified to testify. *Testosterone*, 2017 WL 1836443, at *15. Plaintiffs note, correctly, that being well qualified is no basis for precluding the expert's opinions under Rule 702. Doc. 7805 at 13. Plaintiffs also make clear that Dr. Kessler will not purport to be a current FDA official or present his opinions as having the "imprimatur" of the FDA. *Id.* at 13 n.5. If Dr. Kessler attempts to do so at trial, Defendants may object and make the record clear through cross-examination. *See Testosterone*, 2017 WL 1836443, at *15 ("if an expert comes across as a know-it-all, he tends not to be believed, and cross-examination is a sufficient check"). Moreover, the jury will be informed that the Court, not Dr. Kessler nor any other witness, will instruct the jury on the law.

B. Narrative Testimony.

Defendants contend that Dr. Kessler's reports and attached schedules constitute a sprawling factual narrative, and his testimony at trial will serve only as an impermissible end-run around the orderly admission of evidence. Doc. 7309 at 7-9. But Defendants may object at trial if Dr. Kessler begins simply regurgitating facts instead of using relevant facts to support for his expert opinions. *See Wells*, 2013 WL 7208221, at *2; *In re Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La.

Jan. 10, 2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial."). Furthermore, the Court notes that narrative testimony is appropriate in some circumstances. *See Yasmin*, 2011 WL 6302287, at *13; *Testosterone*, 2017 WL 1836443, at *15. Whether it will be proper during any part of Dr. Kessler's testimony must be determined at trial.[5]

C. Opinions on Bard's FDA Disclosures.

Defendants contend that Dr. Kessler's opinions about what the FDA may have done with additional information are irrelevant and speculative. Doc. 7309 at 9-10. But such testimony is relevant to Defendants' defense that they are not liable because the FDA gave its blessing to Bard filters and labels. And, as a former Commissioner of the FDA, Dr. Kessler is qualified to opine about what a reasonable FDA official would have done with additional information. His testimony concerning these matters is sufficiently reliable for purposes of admissibility under Rule 702. *See Yasmin*, 2011 WL 6302287, at *13; *Bard Pelvic Repair Sys.*, 948 F. Supp. 2d at 630 ("Dr. Kessler may offer expert opinions related to Bard's disclosures to the FDA, as long as his opinions do not impermissibly draw legal conclusions."); *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *19 (E.D. Pa. Feb. 1, 2001) (regulatory expert was "qualified to testify as to what reasonable FDA officials . . . would do with adverse event information"). Whether it is relevant will depend on the nature of Defendants' FDA defense.[6]

D. Opinions on IVC Filter Design, Testing, and Causation.

Defendants object to Dr. Kessler opining on the design and testing of IVC filters.

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[5] In their reply brief, Defendants cite cases for the proposition that Dr. Kessler's report has an "analytical gap" between his factual narratives and regulatory analysis. Doc. 8231 at 4-5. But those cases were addressing the reports of Dr. Parisian, not Dr. Kessler. *See Trasylol*, 709 F. Supp. 2d at 1347; *Lopez*, 2011 WL 1897548, at *10; *Mirena*, 169 F. Supp. 3d at 478; *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 13022172, at *9 (S.D. Ohio Oct. 2, 2015) (S.D.N.Y. 2016). Defendants cite no case that has excluded Dr. Kessler from testifying at trial based on an unreliable methodology or failure to reliably apply the method to the facts of the case. Nor did Defendants raise this analytical-gap issue in their motion.

[6] Defendants' contention that Dr. Kessler's opinions are preempted under *Buckman* (Doc. 7309 at 10-11), is without merit for reasons set forth above.

Doc. 7309 at 11-12. Plaintiffs concede that Dr. Kessler is not qualified to opine that Bard filters were defectively designed, and contend that he is not directly testifying about the adequacy of Bard's testing. Doc. 7805 at 20. Plaintiffs claim that Dr. Kessler discusses filter specifications only in the context of his opinions regarding regulatory compliance. *Id.*

The Court cannot, on the present record, determine whether any specific testimony in this regard should be excluded. Defendants may object at trial if they believe Dr. Kessler is offering impermissible opinions as to the design or testing of Bard filters.

Defendants also object to any opinion that Bard failed to warn physicians about an increased risk of filter complications. As explained above, Dr. Kessler may not render legal conclusions concerning Plaintiffs' state law claims, including the failure to warn claim. The Court may permit Dr. Kessler, as an FDA expert, to opine that the FDA would not have cleared a particular warning if certain information had been disclosed, but Dr. Kessler may not venture outside his area of expertise and opine about the warnings a manufacturer should have given physicians practicing in a specialized area of medicine for purposes of state tort law. *See Bard Pelvic Repair Sys*, 948 F. Supp. 2d at 629.

E. Opinions Regarding Intent and Ethics.

Defendants argue that Dr. Kessler should not be allowed to opine about Bard's intent or ethics. Doc. 7309 at 12-13. The Court agrees. "Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004). Similarly, "[p]ersonal views on corporate ethics and morality are not expert opinions." *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007). Neither Dr. Kessler, nor any other expert (on either side of the case), will be permitted to opine on intent or ethics. *See In re Diet Drugs*, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) (excluding testimony that a pharmaceutical company's conduct was motivated by a desire to increase profits); *Testosterone*, 2017 WL 1836443, at *15 ("[Dr. Kessler] offers a framework by which the jury can assess what [the manufacturer] intended via its

marketing. But although Dr. Kessler may walk up to this line, he may not cross it; he cannot offer an opinion or conclusion about what [the manufacturer] intended.").

F. Summary for Dr. Kessler.

Dr. Kessler is qualified to opine on FDA regulatory issues that relate to Bard filters, and his testimony in this regard would prove helpful to the jury. But no expert, including Dr. Kessler, will be permitted to give ultimate legal opinions on state law claims, improperly narrate or regurgitate facts, or speculate about motives or intent.

IT IS ORDERED that Defendants' motions to exclude the opinions Drs. Suzanne Parisian and David Kessler (Docs. 7308, 7309) are **granted in part** and **denied in part** as set forth in this order.

Dated this 21st day of December, 2017.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed motions to exclude the opinions of Drs. Thomas Kinney, Anne Christine Roberts, and Sanjeeva Kalva. Doc. 7296. The motion is fully briefed, and the Court heard arguments on December 15, 2017. The Court will grant the motion in part.

I. Background.

Each Plaintiff in this MDL received an implant of a Bard IVC filter and claims that the filter is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations,

contending that complication rates for Bard filters are comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

The parties intend to use various expert witnesses at trial, including medical professionals. The doctors subject to the present motion are interventional radiologists whom Plaintiffs have identified as expert witnesses on various issues in this MDL. Defendants ask the Court to exclude four categories of opinions from these experts: (1) their reliance on expert reports of other doctors in forming their opinions; (2) their "summaries and editorials" concerning deposition testimony and a small percentage of the internal Bard documents produced in the litigation; (3) opinions about the "reasonable expectations" of physicians and how a "reasonable physician" would act upon receiving certain information regarding Bard filters; and (4) opinions about IVC filter engineering and the suitability of Bard's bench testing of its filters. *Id.* at 2-3. Plaintiffs oppose the motion. Doc. 7812. The Court will address each of Defendants' arguments.

II. Legal Standard.

Under Rule 702, an expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). The proponent of expert testimony has the ultimate burden of showing, by a preponderance of the evidence, that the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements and the Court's gatekeeping role apply to all expert testimony, not just scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

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III. Discussion.

A. Reliance on Other Expert Reports and Bard Documents.

Without identifying any particular opinion or a specific portion of the doctors' expert report (*see* Doc. 7301), Defendants ask the Court to preclude the doctors from providing any testimony that relies on the report of another expert or on internal Bard documents. Defendants assert that these are not sources of information on which doctors normally would rely as required by Federal Rule of Evidence 703. The Court is not persuaded.

The rule for one expert's reliance on another expert's opinion has been well summarized by Judge Selna:

> [E]xpert opinions may find a basis in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert. Indeed, this is common in technical fields. For example, a physician may rely for a diagnosis on an x-ray taken by a radiologist, even though the physician is not an expert in radiology. There is no general requirement that the underlying expert testify as well. There are limits to this general rule, however. Where the soundness of the underlying expert judgment is in issue, the testifying expert cannot merely act as a conduit for the underlying expert's opinion. Moreover, more scrutiny will be given to an expert's reliance on the information or analysis of another expert where the other expert opinions were developed for the purpose of litigation.

In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig., 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013) (quotation marks, citation, and brackets omitted); *see also E. Allen Reeves, Inc. v. Michael Graves & Assocs., Inc.*, No. 10-1393 (MAS), 2015 WL 105825, at *5 (D.N.J. Jan. 7, 2015) ("An expert . . . may rely on the opinion of another expert in formulating his or her opinion."); *Eaves v. United States*, No. 4:07-CV-118-M, 2009 WL 3754176, at *9 (W.D. Ky. Nov. 5, 2009) (denying motion to preclude expert testimony because experts may rely upon the opinions of other experts); *Weinstein's Federal Evidence*, § 703.04[3] (2017) (Rule 703 permits experts to rely on "[o]pinions of other experts") (citing cases). Thus, the Court does not agree with Defendants' assertion that some or all of the doctors' opinions must be excluded because

they cite, refer to, or even rely on the opinions of other experts in this litigation. The doctors will not be permitted to parrot the opinions of other experts or to vouch for those experts, but they can rely on opinions stated by other experts.

Nor can the Court conclude that the doctors' opinions should be excluded or limited because they rely on internal Bard documents. Those documents are factual evidence in this case, and experts clearly are permitted to take factual evidence into account. Rule 702 requires that experts base their testimony on sufficient facts and apply their expertise "to the facts of the case." Fed. R. Evid. 702(b), (d). Indeed, the first sentence of Rule 703 specifically states that "[a]n expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." The Court cannot accept Defendants' suggestion that an expert cannot rely on a factual source unless the expert previously relied on that source in his or her medical practice. *See Weinstein's Federal Evidence* § 703.04[3] (experts may rely on interviews, reports prepared by third parties, clinical and other studies, business, financial, and accounting records, and general knowledge or experience) (citing cases).[1]

The parties disagree on the extent to which the doctors reviewed the factual material on which they rely. Defendants contend that the doctors relied largely on Dr. Kessler's summary of relevant documents and did not conduct their own independent review of Bard documents. Doc. 7296 at 6. Plaintiffs disagree, asserting that the doctors conducted a thorough evaluation of the documents supporting the opinions of the other experts. Doc. 7812 at 7-8. But even if the doctors did not review every relevant Bard document (Defendants do not identify any they overlooked) and relied to some extent on Dr. Kessler's extensive chronology and summary, the Court cannot conclude that this renders their opinions inadmissible. Their opinions clearly are based on their expertise as interventional radiologists, the doctor's testimony will be confined to their area of

[1] In a footnote, Defendants ask that the doctors be precluded from using the schedules attached to their report during their testimony. Doc. 7296 at 5 n.1. The Court need not resolve this issue because Plaintiffs state that the doctors "will not refer to the schedules while testifying[.]" Doc. 7812 at 7 n.7.

expertise, and if Defendants believe the opinions are based on a slanted or inaccurate view of the facts, they certainly will be free to demonstrate that during cross examination.

Nor is the Court persuaded by Defendants' assertion that these experts cite less than 0.0028% of Bard's internal documents. The actual percentage of a party's documents relied on for trial is always exceedingly small, especially in these days of electronically stored information when the amount of available information greatly exceeds the amount of information that reasonably can be used in a trial.

B. Summaries and Editorials.

Defendants ask the Court to preclude the doctors from "quoting, summarizing, and offering editorials about deposition testimony and Bard's internal documents," asserting that such testimony would be unhelpful to the jury. Doc. 7296 at 7. Plaintiffs respond that the doctors "will not testify solely as 'summarizers' of documents. Instead, their proposed testimony about Bard's internal documents will provide a contextual and factual foundation for their opinions as interventional radiologists[.]" Doc. 7812 at 11.

Line drawing in the context of such generalized arguments is not possible, and Defendants identify no specific testimony that the Court should exclude. Defendants do cite to a few paragraphs in the doctors' 115-page expert report, but otherwise make no specific request regarding testimony to be excluded.

Experts on both sides of this case will be permitted to state opinions within their areas of expertise and to explain the factual, medical, technical, or scientific bases for those opinions. This testimony will be helpful to the jury and necessarily will require the experts to discuss some factual evidence. Experts will not be permitted to engage in lengthy factual narratives that are not necessary to the jury's understanding of their opinions, nor will they be permitted to gratuitously comment on factual evidence or present what are essentially lawyer arguments with regard to factual testimony. Rules 703 and 705 will apply to any expert's explanation of opinions. In short, the Court will seek to strike the proper balance at trial between (a) allowing experts to reasonably explain their opinions in a manner helpful to the jury and (b) avoiding unnecessary

factual recitation or argument. More detailed rulings are not possible at this stage of the proceeding. *See In re Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial."); *In re Yasmin & YAZ Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011) (noting that issues concerning narrative testimony should be "decided at trial in context specific situations").

C. Opinions on Reasonable Expectations and Physicians.

Defendants ask the Court to exclude opinions as to what a physician reasonably expects to be told about the risks of IVC filters, or what a reasonable physician would do with certain adverse information about the devices. Doc. 7296 at 9-10; *see* Doc. 7301 ¶¶ 3, 7, 65-66, 73, 75-76, 182. Plaintiffs counter that the doctors are qualified to offer such opinions given their expertise in interventional radiology and use of IVC filters, and that the opinions have a reliable foundation. Doc. 7812 at 12-15.

Defendants challenge these opinions because "they are not grounded in any reliable source of authority, they have not been tested or peer reviewed, they have no known rate of error, they have not been published, and the physicians have not identified their view as generally accepted in the medical community." Doc. 7296 at 2-3, 9. But these factors are neither exclusive nor dispositive in a Rule 702 inquiry, *see Daubert*, 509 U.S. at 593-94, and "may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (quoting *White v. Ford Motor Co.*, 312 F.3d 998, 1007 (9th Cir. 2002)). As the Supreme Court has explained, although some expert testimony "rests upon scientific foundations," in other cases "the relevant reliability concerns may focus upon personal knowledge or experience. *Daubert* makes clear that the factors it mentions do *not* constitute a definitive checklist or test." *Kumho Tire*, 526 U.S. at 150 (citations omitted; emphasis in original). The Ninth Circuit likewise holds that "[t]he *Daubert* factors (peer review, publication, potential error rate, etc.) simply are

not applicable to [testimony] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000).

This holds true for much medical testimony. As the Ninth Circuit has noted, medicine "is not a science but a learned profession, deeply rooted in a number of sciences and charged with the obligation to apply them for man's benefit." *Primiano*, 598 F.3d at 565 (quotation marks and citation omitted). "Despite the importance of evidence-based medicine, much of medical decision-making relies on judgment – a process that is difficult to quantify or even to assess qualitatively." *Id.* (quotation marks and citation omitted). Thus, "a doctor's experience might be good reason to admit his testimony." *Id.* at 566 (citing *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 982 (6th Cir. 2004); *Schneider v. Fried*, 320 F.3d 396, 406-07 (3d Cir. 2003)).

Defendants do not dispute that the doctors are highly qualified experts in interventional radiology and the use of IVC filters. In Defendants' own words, the doctors "are practicing interventional radiologists, members of radiological societies, reviewers for radiological journals, and authors of articles and presentations concerning the clinical use of IVC filters." Doc. 7296 at 2. Under Rule 702 and *Daubert*, expert testimony "is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Primiano*, 598 F.3d at 565 (citation omitted). The Court finds that the doctors' knowledge and experience in the field of interventional radiology and the use of IVC filters in patients form a sufficient foundation for their opinions.

In support of their argument that these experts cannot state opinions on what doctors "reasonably expect" to be told about the risks of IVC filters, or what a "reasonable physician" would do with certain adverse information about the devices, Defendants cite several cases. The Court is not persuaded, however, that the cases fully support Defendants' position.

The court in *In re Diet Drugs*, No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000), held that two doctors were not qualified to opine "about what all doctors generally consider in making prescription decisions." *Id.* at *11. The basis for this conclusion is not entirely clear from the court's decision, but it appears that the court was not comfortable with the scope of the opinion – what "all doctors" think. The court did not address whether the doctors could opine on what information a reasonable physician in a particular specialty might find important.

In *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001), the same judge, in the same proceeding, held that an FDA-expert physician was "not qualified to opine on what decisions would have been made by the numerous physicians who prescribed diet drugs had they been provided with different labeling information." *Id.* at *18. The court explained: "Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge." *Id.* The court thus appeared to recognize that an expert could testify about what physicians in general expect to see on a label – testimony very similar to Plaintiffs' proposal that Drs. Kinney, Roberts, and Kalva testify about what interventional radiologists expect in medical product disclosures.

The third case cited by Defendants, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004), relied on the *Diet Drugs* decisions to hold that a doctor could not testify that physicians would not have prescribed a particular drug if the manufacturer had made full disclosures. The court explained: "Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge." *Id.* at 557. Again, the court recognized that the expert could testify about what physicians in general expect to see on a label.

The Court cannot conclude from these cases that Drs. Kinney, Roberts, and Kalva should be precluded from testifying about disclosures that reasonable radiologists expect

to receive from manufacturers of IVC filters. Such testimony, if relevant, appears to be well within their expertise and experience, and the Court can identify no basis under Rule 702 for precluding it.

Whether the doctors should also be permitted to testify about what doctors would have done with additional information seems more problematic. Whether and when to use a particular product appears to be a more fact- and patient-specific decision, not amenable to broad generalizations. The propriety of testimony on this subject will depend heavily on the context and relevancy of the question. The Court will need to draw these lines during trial.

D. Opinions on Engineering, Bench Testing, and Filter Performance.

Defendants note that the doctors render various opinions about filter engineering and the suitability of Bard's testing procedures. Defendants argue that the doctors are not qualified to render such opinions. Doc. 7296 at 13. The Court agrees in part.

Dr. Kinney received a master's degree in mechanical engineering in 1979 and accepted a job with a physician designing angioplasty balloons, vascular clams, and a cardioplagia jacket for use during open heart surgery. In 1983, Dr. Kinney entered medical school and continued to work with the cardioplagia jackets as part of his independent study. Since graduating from medical school, Dr. Kinney has not done any medical device design work, and he has never designed bench top testing. Doc. 7296 at 12 (citing record). Dr. Kinney has served as chair of data safety monitoring boards for clinical trials involving other IVC filters, and has published studies and review articles on IVC filters, including IVC design function. Doc. 7812 at 15-16 (citing record).

Drs. Roberts and Kalva are clinical physicians with no background in engineering or actual bench testing of medical devices. The doctors have studied IVC filters and have seen filter failures in their medical practices. Dr. Kalva has published studies on the function, use, and complications of IVC filters, and is involved in developing an undisclosed patent for an IVC filter design. *Id.*

Defendants assert that the doctors are not qualified to opine on a number of matters in their export report. The Court's task in ruling on this motion is complicated by the fact that Defendants cite specific paragraphs of the doctors' report that include both mechanical and medical opinions, and Plaintiffs' response does not address many of the paragraphs cited. For example, Defendants object to report paragraphs 115 (opining about how changing of the size of the diameter of the Bard filter impacted the radial force for the hook to engage the cava wall), 120 (opining about pressure gradient bench testing), 127 (opining about fatigue resistance testing), 133 and 167-68 (opining about finite element analysis of Bard's filters), and 135-138 (opining about how fracture of filters can impact forces and loads on the filter). Doc. 7296 at 13. Plaintiffs' response jumps over these paragraphs entirely, citing instead to paragraphs 59-77 and 141-182 of the report. Doc. 7812. As these ships pass in the night, the Court is left with little ability to reach specific conclusions.

It appears clear, however, that the doctors are not qualified to testify on technical matters such as those set forth in their report at paragraphs 115 (engineering and design implications related to cephalad angulation of hooks), 120 (gradient thresholds, safety margins, and "[c]ommon safety factors used in engineering,"), 127 (evaluation of specific fatigue resistance testing), 133 (opinion that engineers used too low a deflection), and 138 (opinion on improper balance struck in Recovery filter design). Doc. 7301. Drs. Roberts and Kalva have no training or experience on such matters, and Dr. Kinney's training and experience in this field are more than 30 years old. *See In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327, 2016 WL 4500765, at *5 (S.D. W. Va. Aug. 26, 2016) ("Dr. Rosenzweig is not qualified to opine that Ethicon's testing was insufficient. There is no indication that Dr. Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake."); *Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (physician's opinions about manufacturing defects in knee replacement components went "well beyond the

'reasonable confines' of his clinical expertise" even though he had significant clinical experience with the device).

Other somewhat technical opinions may be within the expertise of these doctors. They may be qualified, for example, to opine that filtering for blood clots is essentially a geometric issue, and that the loss of a filter arm or leg due to fracture results in larger gaps and places greater forces on the other arms and legs. Doc. 7301 ¶ 135. Or they may be qualified to explain that the changes to the Recovery filter are primarily dimensional, and opine as to what the changes suggest in terms of filter performance. *Id.* ¶ 156. Such opinions might reasonably be based on expertise and experience in implanting, monitoring, and removing IVC filters.

The Court cannot be more precise at this point. Although the Court generally concludes that Drs. Kinney, Kalva, and Roberts are not experts in mechanical design and testing, more specific rulings will have to be made during trial.

IT IS ORDERED that Defendants' motion to exclude expert opinions (Doc. 7296) is **granted in part** and **denied in part** as set forth in this order.

Dated this 22nd day of December, 2017.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Dr. Mark Eisenberg. Doc. 7291. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard IVC filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about

the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

Plaintiffs have identified Dr. Eisenberg as an expert witness on various issues, including concerns about the safety and efficacy of Bard filters, Bard's obligations to perform safety studies and inform physicians and patients about them, whether the filters were as safe and effective as their predicate devices, and the interpretation of certain clinical studies. Dr. Eisenberg is a board-certified interventional cardiologist. He regularly treats patients with deep vein thromboses and pulmonary emboli, including patients implanted with IVC filters and those who may be candidates for implantations, although he does not implant filters himself. He is also a clinical epidemiologist, having obtained a master's degree from the Harvard School of Public Health. Doc. 7293 at 4-5.[1]

Defendants challenge Dr. Eisenberg's opinions on several grounds. Defendants contend that his opinions about Bard's responsibilities and alleged unethical conduct are not the proper subject of expert testimony, and that he is not qualified to render such opinions. Doc. 7291 at 3-4, 6-11. Defendants make the same arguments as to opinions regarding Bard's knowledge, motives, intent, and state of mind. *Id.* at 11-13. Defendants further argue that factual narratives and "common sense" opinions will not assist the jury. *Id.* at 13-18. Finally, Defendants argue that Dr. Eisenberg cannot speak on behalf of all physicians and patients. *Id.* The Court will address each argument.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Opinions Regarding Ethics and State of Mind.

Plaintiffs agree that Dr. Eisenberg may not opine on Bard's "ethics, motivations, intentions, and state of mind" (Doc. 7810 at 2), but the parties disagree on whether Plaintiffs intend to have him testify on those topics. Plaintiffs assert that his 47-page report contains no opinion that Bard's conduct was unethical, but instead states opinions on "the evidence concerning safety and efficacy of Bard's filters, the information that physicians and patients need for proper informed consent and medical decision-making, and an evaluation of Bard's disclosures of the information it had." Doc. 7810 at 2. Defendants counter that Plaintiffs are attempting to recast Dr. Eisenberg's report and sworn testimony as anything other than ethics opinions, and note that another court has rejected a similar attempt. Doc. 8222 at 2; *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-1928, 2010 WL 1489793, at *8-9 (S.D. Fla. Feb. 24, 2010).

The Court does not find it helpful to cast the issue in terms of ethics vs. non-ethics, but instead will focus on Dr. Eisenberg's specific assertions and the bases for them. He opines that, in light of various "safety signals," Bard had a responsibility to perform large prospective safety studies and randomized controlled clinical trials. Doc. 7293 ¶¶ 30, 34,

197-98, 202, 207, 213. He devotes an entire section of his report to Bard's responsibility to do safety studies. *Id.* ¶¶ 193-210 (§ IV.K). He asserts that Bard did not conduct such studies, but instead "downplayed the documented high rates of adverse events with the Recovery and G2 filters" and had a "corporate policy to not share any of these complication rate analyses with anyone outside the company." *Id.* ¶¶ 85-86, 173. He opines that Bard looked "for ways to avoid being forthright" and spent "time, money and company resources on a media company and PR for 'spin control.'" *Id.* ¶ 95. He claims that Bard performed no studies because it did not want to know the answer – "If you don't want to know the answer, then don't look" – and that Bard "effectively allowed patients to be experimental subjects." *Id.* ¶¶ 35-36.

In short, Dr. Eisenberg expresses strong opinions on what Bard knew, what Bard was obligated to do in light of that knowledge, and how Bard failed to fulfill its obligation and chose instead to mislead physicians. The Court concludes that the cited bases for these opinions either are not relevant, fail to satisfy Rule 702(c), or are outside his area of expertise.

Dr. Eisenberg cites the American Medical Association Code of Medical Ethics and an American College of Radiology practice guideline for informed consent. Doc. 7293 ¶ 24-26. These documents contain ethical and practice guidance for doctors; they say nothing about the legal responsibilities of device manufacturers. Later, Dr. Eisenberg cites an FDA guidance document and a World Health Organization report on pharmacovigilance (*id.* ¶ 42), but he does not purport to be an FDA regulatory expert or an expert in pharmacovigilance. Doc. 7291-2 at 11-12. Dr. Eisenberg also cites an internal Bard Standard Operating Procedure and states: "In my opinion, this Standard Operating Procedure sets a *minimum standard* for when a device failure rate is unacceptable and must be corrected." Doc. 7293 ¶ 49 (emphasis added). But his only explanation for the source of this "minimum standard" is what a "reasonably prudent physician" would expect of a medical device manufacturer. *Id.* What a reasonably prudent physician would expect may be relevant in a medical malpractice case where the

medical standard of care is at issue, but Plaintiffs cite no authority to show that it sets the legal standard for medical device manufacturers under the state tort laws applicable in this MDL proceeding. Finally, Dr. Eisenberg states that the standards underlying his opinions "form the foundation of our medical system" (*id.* ¶ 42), but citing such imprecise and general standards does not satisfy Rule 702(c).

Dr. Eisenberg's deposition makes clear that his opinions are based not on any "scientific, technical, or otherwise specialized knowledge" as required by Rule 702(a), but on his own personal views about proper corporate behavior. He admitted that it was fair to describe his opinions as "based on what [he] believe[s] a responsible, ethical and moral device manufacturer" would have done. Doc. 7291-2 at 28 (Dep. Tr. 89:21-15). Personal views on proper corporate behavior are not appropriate expert opinions. *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007); *see also Trasylol*, 2010 WL 1489793, at *9 (finding Dr. Eisenberg's opinions on Bard's responsibilities inadmissible under Rule 702 because they were based on speculation and the doctor's subjective beliefs rather than any objective standard or specialized knowledge); *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 542-43 (S.D.N.Y. 2004) ("The opinions of plaintiffs' witnesses, however distinguished these individuals may be as physicians and scientists, concerning the ethical obligations of pharmaceutical companies and whether the defendants' conduct was ethical are inadmissible[.]"); Doc. 9433 at 17 (holding that no expert, on either side, will be permitted to opine on intent or ethics).

Dr. Eisenberg also expresses opinions about what Bard knew based on various internal documents, how Bard tracked adverse event reports, and what Bard failed to take into account in designing its filters. *See, e.g.*, Doc. 7293 ¶¶ 31, 69, 75, 82-85, 97, 106, 112, 115. But Dr. Eisenberg is not an expert on corporate communications, behavior, or regulation, and he admits that he has no "specific training looking at company documents and identifying what the company knows or doesn't know[.]" Doc. 7291-3 at 4-5 (Dep. Tr. 59:5-60:67). Nor has he conducted any study of Bard internal operations, information

gathering, or design processes. To the extent Dr. Eisenberg "offers opinions on Bard's intent, state of mind, or motivations, this testimony is outside the bounds of appropriate expert testimony." *Tillman v. C. R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1326 (M.D. Fla. 2015).

Plaintiffs assert that Dr. Eisenberg should be allowed to testify, within scope of his specialized knowledge, regarding the information physicians must possess if they are to obtain informed consent from their patients. Doc. 7810 at 8. But even if such physician information is relevant for the jury to decide whether Bard is liable for a failure to warn, it is not relevant in the way Dr. Eisenberg intends to use it – to establish Bard's legal obligations. It cannot be used, as Plaintiffs propose, to establish "what steps must be taken" by a medical device manufacturer "in response to safety signals in order to improve patient safety." *Id.* The Court will instruct the jury on how to determine Defendants' duty in this case, and testimony from FDA regulatory experts may be relevant to that determination. But Dr. Eisenberg's personal opinions cannot supply the standard.

In summary, Dr. Eisenberg will not be permitted to render opinions about what Bard did or should have done; to testify about Bard's corporate knowledge, internal conduct, or intent; or to testify about what steps must be taken by a medical device manufacturer in response to safety signals or to improve patient safety. He is an interventional cardiologist with training in clinical epidemiology; Plaintiffs have not shown that he is qualified to testify on these subjects or that his proposed testimony is based on reliable principles and methods. Fed. R. Evid. 702.

B. Narrative Testimony.

Dr. Eisenberg's report includes a discussion of the history of Bard filters and internal company documents. *See, e.g.*, Doc. 7293 ¶¶ 56-72. Defendants contend that these factual narratives are not helpful to the jury or appropriate subjects of expert testimony, and serve only to circumvent the proper presentation of evidence at trial. Doc. 7291 at 13-16. The Court previously has explained that although experts in this

case may explain the factual basis for their opinions, they will not be permitted to gratuitously comment on factual evidence or engage in lengthy factual narratives not necessary to the jury's understanding of their opinions. Doc. 9434 at 4. At trial, the Court will seek to strike the proper balance between allowing experts to reasonably explain their opinions in a manner helpful to the jury, and avoiding unnecessary factual recitation or argument. *See id.* The Court cannot draw lines now.

C. "Common Sense" Opinions.

Defendants cite portions of Dr. Eisenberg's deposition where he testified that the significance of some Bard internal documents would be readily apparent to the jury, or where he expressed views based on common sense. Doc. 7291 at 18. To the extent Plaintiffs intend to have Dr. Eisenberg review internal Bard documents and simply confirm what he believes they would show to any reasonable juror, or state what he believes they show as a matter of common sense, such testimony will not be permitted. It is not based on expertise and would not assist the jury as required by Rule 702(a).

D. Opinions About Other Physicians.

Defendants ask the Court to exclude Dr. Eisenberg's opinions about the reasonable expectations all physicians have of medical device companies like Bard. Doc. 7291 at 16-17. Plaintiffs counter that Dr. Eisenberg opines about informed consent standards, not other physicians' states of mind. Doc. 7810 at 18. Plaintiffs assert that "[w]hile Bard focuses on whether Dr. Eisenberg can testify to how other physicians would react to complication rates, the principle focus of [his] testimony is what physician's need to perform their duties[.]" *Id.* at 19.

As noted above, Dr. Eisenberg will not be allowed to use physician expectations to establish Bard's legal obligations.

Furthermore, throughout his report Dr. Eisenberg offers opinions about what other physicians would think and do with certain information about Bard filters. He opines that "physicians who use IVC filters would agree that Bard's standard [operating procedure] is at best a minimum standard" (Doc. 7293 ¶ 49), that physicians "who became aware of

the adverse event rates that Bard was observing would likely have stopped using these devices immediately" (¶ 86), and that the adverse event rates "would have persuaded most physicians from using [the Recovery] device" (¶ 137). But Dr. Eisenberg has never implanted or removed an IVC filter and does not claim to be an expert on IVC filters. Doc. 7291-2 at 5-6. He has done no research on IVC filters prior to his retention in this litigation. *Id.* at 5. He lacks the specialized knowledge and experience needed to opine about how IVC-filter physicians would respond to facts at issue in this case, and will not be permitted to give such opinions. Fed. R. Evid. 702.

IT IS ORDERED that Defendants' motion to exclude the opinions of Dr. Mark Eisenberg (Doc. 7291) is **granted** to the extent set forth in this order.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Dr. Derek Muehrcke. Doc. 7304. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard IVC filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about

the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

The parties intend to use various expert witnesses at trial, including medical professionals. Plaintiffs have identified Dr. Muehrcke, a cardiothoracic surgeon, as an expert witness on various issues in each of the five cases selected for bellwether trials. He has prepared case-specific reports that share certain opinions in common. Doc. 7307. Defendants ask the Court to exclude seven categories of opinions: (1) Bard filters have design defects; (2) adoption of opinions of other experts; (3) reasonable expectations of physicians regarding filter performance; (4) Bard filters have an "unacceptable" risk of caudal migration; (5) Bard acted unethically in selling its filters; (6) Bard's state of mind, motive, and intent; and (7) the failure of Plaintiff Lisa Hyde's filter resulted in an increased risk for arrhythmias and sudden death, and the need for an implantable defibrillator. Doc. 7304 at 2.[1] The Court will address each category.[2]

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v.*

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[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

[2] The bellwether cases are those brought by Plaintiffs Sherr-Una Booker, Lisa Hyde, Doris Jones, Carol Kruse, and Debra Mulkey.

Merrell Dow Pharm., Inc., 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Design Defects.

Dr. Muehrcke is a cardiothoracic surgeon who received his specialty training at Harvard Medical School and Massachusetts General Hospital. Doc. 7307 at 2. He serves as Chief of Cardiothoracic Surgery at Flagler Hospital in St. Augustine, Florida, and is part of a private medical group that performs heart surgeries at seven area hospitals. *Id.* at 3. He implants or removes nearly 50 IVC filters per year, and has more than 20 years' experience treating patients with IVC filters. *Id.* at 2-3.

Defendants argue that Dr. Muehrcke is not qualified to offer design related opinions because he has never designed or tested an IVC filter and has no background in engineering, metallurgy, or materials science. Doc. 7304 at 3. Defendants ask the Court to exclude this design opinion:

> Due to the filters [sic] inadequate design, Ms. Booker's filter tilted, became embedded in the vena cava, punctured through the vena cava and surrounding organs and structures, multiple strut fractures occurred, and filter fragments embolized to the heart. Specifically, the device's inadequate migration resistance, and lack of strength and stability, caused by its weak anchoring hooks and lack of radial force and inadequate leg span to accommodate vessel distention were substantial factors in causing this device to migrate in a caudal direction, tilt, perforate the vena cava, and fracture. In reaching this opinion, I reviewed Ms. Booker's medical records and radiology, and performed a differential diagnosis, and there is no other reasonable cause for the failures of the filter.

Doc. 7307 at 10. Dr. Muehrcke offers similar opinions in other bellwether cases. *See* Docs. 7307-1 at 9 (inadequate migration resistance and lack of strength and stability

caused Plaintiff Hyde's G2 filter to migrate, tilt, perforate the IVC, and fracture); 7307-2 at 9 (lack of strength and stability caused Plaintiff Jones's Eclipse filter to fracture); 7307-3 at 9 (inadequate migration resistance and lack of strength and stability caused Plaintiff Kruse's G2 filter to migrate, tilt, and fracture).

The quoted opinion states that several specific structural characteristics of the G2 filter were substantial factors in causing it to migrate, tilt, perforate the IVC, and fracture. These include the filter's inadequate migration resistance and lack of strength and stability caused by its (1) weak anchoring hooks, (2) lack of radial force, and (3) inadequate leg span. Doc. 7307 at 10. Clearly, Dr. Muehrcke is not qualified to testify about anchoring hooks, radial force, or leg span as an engineer, metallurgist, or product designer – he claims none of those qualifications. Thus, to the extent Plaintiffs offer his testimony as a design or engineering expert on characteristics of IVC filters, he is not qualified and will be excluded.

But Dr. Muehrcke identifies a different basis for his opinion: "In reaching this opinion, I reviewed Ms. Booker's medical records and radiology, and performed a differential diagnosis, and there is no other reasonable cause for the failures of the filter." *Id.* In other words, he reviewed Booker's medical records and the x-rays of her filter and, as a thoracic surgeon with years of experience in implanting and removing IVCs, could find no other cause for the failure of her Bard filter than inadequate migration resistance. Dr. Muehrcke is qualified to give this opinion. As a trained and experienced thoracic surgeon who regularly uses IVC filters and engages in differential diagnoses, he is qualified to opine on factors that caused a filter's failure – in this case, an inability to resist migration in the IVC. Whether he can also opine on more specific design problems such as a lack of strength and stability caused by weak anchoring hooks, lack of radial force, and inadequate leg span depends on whether his medical training and experience provides expertise on these specific aspects of IVC filters, something the Court cannot determine on this record.

The Court will permit Dr. Muehrcke to opine that Ms. Booker's problems arose because the Bard filter's design had inadequate migration resistance. Whether he can provide more specific testimony on the cause of this inadequacy will depend on the foundation laid at trial.

B. Reliance on Other Expert Reports.

Defendants contend that Dr. Muehrcke's opinions are unreliable because he adopts the opinions of Drs. Kinney, Kalva, Roberts, and Eisenberg. Doc. 7304 at 5-6. As the Court previously has found, Rule 703 permits experts to rely on opinions of other experts. *See* Doc. 9434 at 3-4 (citing *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013); *E. Allen Reeves, Inc. v. Michael Graves & Assocs., Inc.*, No. 10-1393 (MAS), 2015 WL 105825, at *5 (D.N.J. Jan. 7, 2015); *Eaves v. United States*, No. 4:07-CV-118-M, 2009 WL 3754176, at *9 (W.D. Ky. Nov. 5, 2009)). Neither Dr. Muehrcke nor any other expert will be permitted at trial to simply parrot the opinions of other experts, or to vouch for those experts, but they can rely on opinions stated by other experts.

C. Opinions Regarding the Reasonable Expectations of Physicians.

Dr. Muehrcke offers this opinion in the Booker case:

> Based upon the information available to Bard at the time the filter was implanted in Ms. Booker, it was clear that the risks of the Bard . . . filter exceeded its benefits and that this filter did not perform in a manner reasonably expected by physicians and patients, nor in the manner represented by Bard.
>
> In using Bard's . . . filter, physicians reasonably expected that if the filter was properly placed it would not migrate, tilt, perforate the vena cava and adjacent organs/structures, fracture, or have filter fragments embolize to the heart. In my opinion, because this filter failed in the manner previously described, Ms. Booker was exposed to risks that exceeded any benefits allegedly offered by this particular filter nor would a physician or patient reasonably expect this constellation of failure modes to occur.

Doc. 7307 at 10. Similar opinions are rendered in the other bellwether cases. *See* Docs. 7307-1 – 7307-3 at 9; 7307-4 at 8.

Defendants ask the Court to exclude these opinions on the ground that Dr. Muehrcke cannot speak on behalf of all physicians regarding reasonable expectations of IVC filters. Docs. 7304 at 6-8; 8224 at 7-10. Defendants claim that Dr. Muehrcke is not qualified to offer such opinions and has identified no reliable methodology, noting that he cites no supporting scientific literature, has conducted no survey as to what other physicians think, and acknowledges that the risk-benefit analysis performed by individual physicians is a subjective art form, not a science. *Id*.

Plaintiffs assert that Dr. Muehrcke is not purporting to speak on behalf of other physicians, but instead is offering an opinion about the adequacy of Bard's warnings. Doc. 7813 at 10. Plaintiffs state that in "giving the opinion that the Bard G2 filter 'did not perform in a manner reasonably expected by physicians and patients, nor in the manner represented by Bard,' Dr. Muehrcke is clearly opining that the warnings and other information provided by Bard to physicians was insufficient." *Id.* at 10-11 (quoting Doc. 7307-1 at 9). Plaintiffs further state that "Dr. Muehrcke's opinion – which expressly mentions 'the manner represented by Bard' – is an opinion that Bard did not provide physicians with adequate information about the risks presented by its IVC filters." *Id.* at 11. Plaintiffs conclude by stating that based on his extensive experience implanting and removing IVC filters, Dr. Muehrcke's "warnings opinions" are reliable. *Id.* at 12.

Given this response and Plaintiffs' focus on Dr. Muehrcke's "warnings opinions," it is not clear whether Plaintiffs intend to have Dr. Muehrcke testify at trial about the reasonable expectations of physicians regarding filter performance. He clearly expresses such opinions in each report. *See, e.g.*, Doc. 7307 at 10. He also opines in each report that "the risks of the Bard . . . filter exceeded its benefits" and that each Plaintiff "was exposed to risks that exceeded any benefits allegedly offered by [their] particular filter." *See id.* Plaintiffs do not address these risk-benefit opinions in their response brief.

The admissibility of similar opinions was addressed in a recent order concerning Drs. Kinney, Roberts, and Kalva. Doc. 9434. Given the doctors' qualifications and

experience as interventional radiologists, the Court found that they should not be precluded from testifying about what disclosures reasonable physicians expect to receive from manufacturers of IVC filters. *Id.* at 6-9. With respect to testimony about what physicians would have done with additional information, however, the Court concluded that the admissibility of such testimony must be determined at trial. *Id.* at 9.

The Court reaches similar conclusions regarding Dr. Muehrcke. Defendants do not dispute that Dr. Muehrcke is a well-qualified cardiothoracic surgeon. During the past 20 years, he has implanted and removed hundreds of IVC filters, including those manufactured by Bard. Doc. 7307 at 2-3. Under Rule 702 and *Daubert*, expert testimony "is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Primiano*, 598 F.3d at 565 (citation omitted). The Court finds that Dr. Muehrcke has sufficient knowledge and experience to offer his opinion as to the information reasonable physicians expect to receive from IVC manufacturers, and whether physicians who implant IVC filters reasonably expect a properly implanted filter to tilt, perforate the IVC, or fracture and migrate to neighboring organs. Defendants may, of course, challenge the reliability of these opinions through cross examination or qualified experts of their own.

Dr. Muehrcke's risk-benefit opinions are more problematic. Whether the risks of using a particular medical device outweigh the benefits is a fact- and patient-specific decision not amenable to broad generalizations about what a "reasonable" patient or physician would decide. The propriety of testimony on this subject will depend heavily on the context and relevancy of the question. The Court will make these rulings during trial.

D. Opinions on the "Unacceptable" Risk of Migration.

In his report for the Booker case, Dr. Muehrcke offers this opinion regarding the G2 filter's migration risk:

> Bard had been aware since late 2005/early 2006 of the need to correct the "unacceptable" caudal migration risk with the G2 filter. Bard was also aware that caudal migration leads to tilt, perforation, penetration,

> irretrievability, and fracture. Despite this knowledge, Bard did nothing to inform physicians or patients of these safety risks; choosing instead to launch two more filters, the G2X and Eclipse, prior to launching a filter, the Meridian, that addresses caudal migration. Ms. Booker's filter ultimately failed in the manners expected of the G2 filter – e.g., caudal migration, tilt, irretrievability, perforation/penetration, and fracture – which the Meridian was intended to correct. In my opinion, Bard should have removed the G2 filter from the medical market and medical facilities given its knowledge of the "unacceptable" risk of caudal migration[.]

Doc. 7307 at 8. Similar opinions are set forth in the reports for two other bellwether cases. *See* Docs. 7307-1 at 8 (Hyde), 7307-2 at 8-9 (Jones).[3]

The Court concludes that Dr. Muehrcke should not be permitted to opine on Bard filter failure rates. Even if a physician could be qualified to render such opinions, he has not conducted any study of IVC filter complication rates. Plaintiffs argue that his opinions are based on personal experience with IVC filters and his training and experience as a doctor, but he does not state that he tracked failure rates in his personal cases. Dr. Muehrcke did review a number of medical articles regarding IVC filter complication rates, including the Deso article, which concerned a literature search regarding complications associated with various IVC filter designs. Doc. 7302-2.[4] But even if these articles suggest that Bard filters have higher complication rates than other filters, Dr. Muehrcke does not claim to have taken any steps to verify their conclusions, and merely restating those conclusions does not constitute a reliable basis for rendering an expert opinion under Rule 702. Dr. Muehrcke cannot simply repeat the opinions of others as his own when he has done nothing to verify the accuracy of the opinions. *See In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016) ("[The expert's] opinions . . . do not rely 'in part' on the purported expertise of

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[3] Defendants assert that this opinion also is included in the report for the Mulkey case (Doc. 7304 at 12), but the cited page is not included in the copy of the report filed with the Court (see Doc. 7307-4 at 7-8).

[4] The article is "Evidence-Based Evaluation of [IVC] Filter Complications Based on Filter Type," co-authored by Drs. Steven Deso, Ibrahim Idakoji, and William Kuo, and published in *Seminars in Interventional Radiology* (Vol. 33 at 93-100, No. 2/2016).

other testifying experts. Rather, [the expert] repeats and concurs with their opinions, without additional analysis. The Court does not need an expert to reiterate other experts' testimony.").

His opinion that the G2 filter poses an "unacceptable risk" of caudal migration is based on a Bard internal document. A report titled "G2 Caudal Migration Update," prepared by Bard product quality engineer Natalie Wong, states that in certain circumstances the G2 filter had an "[u]nacceptable risk" of caudal migration per Bard's failure modes and effects analysis. Doc. 7825 at 21. Again, however, Dr. Muehrcke does not identify any steps he has taken to verify the conclusion in the Wong report. Nor does he identify the person or entity to whom the risk he mentions is unacceptable – physicians, patients, medical manufacturers, the FDA, etc. Indeed, in his deposition he steadfastly refused to identify an acceptable failure rate, saying only that it should be as close to zero as possible. Doc. 7304 at 10 (quoting Dep. Tr. 65:2-5).

Dr. Muehrcke could opine, as a treating physician who must make decisions about IVC filter use, that Bard should have disclosed any risks it found in its products that would be unacceptable to doctors and patients. But he cannot opine that Bard filters present an "unacceptable risk" unless that opinion is based on sufficient facts and data he has identified, to which he has applied reliable principles and methods. Fed. R. Evid. 702(b), (c). Merely repeating conclusions in the Wong report as his own opinion does not meet this requirement.

Nor can Dr. Muehrcke opine about the failure rates of Eclipse filters. Plaintiffs identify no study or articles he reviewed on Eclipse failure rates, much less any he verified.

E. Opinions Regarding State of Mind and Ethics.

Defendants argue that Dr. Muehrcke's opinions about what Bard knew or should have done, and Bard's underlying motives and intent, are classic jury questions outside the bounds of appropriate expert testimony. Doc. 7304 at 12-13. Plaintiffs state that the doctor will not opine as to motives or intent, but contend that the degree of Bard's

knowledge about the dangers posed by its filters is relevant to the failure-to-warn claims. Doc. 7813 at 17-18.

Dr. Muehrcke will not be permitted to opine about Bard's knowledge, intent, or ethics. *See* Doc. 9434 at 17. He does not purport to be an expert on corporate information processing and he has not conducted any study of Bard internal operations, information gathering, or corporate ethics. Plaintiffs propose to have him opine about what Bard knew based on selected documents, but identify no expertise that enables him to opine on Bard's knowledge. Dr. Muehrcke may opine that Bard should have provided warnings to physicians and patients if it knew of excess risks, but it will be up to other evidence to show that Bard had such knowledge.

F. Opinions on the Future Medical Risks and Needs in the Hyde Case.

Dr. Muehrcke opines that as a result of the failure of Plaintiff Hyde's G2 filter, she is at risk for arrhythmias and sudden death, and will need an implantable defibrillator. Doc. 7307-1 at 8-9. Defendants challenge this opinion on the ground that Dr. Muehrcke cannot quantify the future medical risks and needs. Doc. 7304 at 13-14. The Court concludes that it will be better able to address this issue in the context of the Hyde trial and after trying a few bellwether cases, and therefore will withhold ruling until the Hyde case is ready for trial. Defendants may reassert their arguments in a motion in limine.

IT IS ORDERED that Defendants' motion to exclude the opinions of Dr. Derek Muehrcke (Doc. 7304) is **granted in part** and **denied in part** as set forth in this order.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Dr. Darren Hurst. Doc. 7302. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about

the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

Plaintiffs have identified Dr. Hurst, an interventional radiologist, as an expert witness on various issues in each of the five cases selected for bellwether trials. He has prepared case-specific reports that share certain opinions in common. Doc. 7306. Defendants ask the Court to exclude three categories of opinions: (1) Bard filters have higher complication rates than other filters and an "unacceptable risk" of caudal migration; (2) Bard ignored safety signals, failed to perform additional studies, and misrepresented the safety and performance of its filters; and (3) Bard failed to communicate to doctors that the Meridian filter should be used instead of the G2X or Eclipse. Doc. 7302 at 2.[1] The Court will address each category.[2]

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). But the trial court acts as a

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

[2] The bellwether cases are those brought by Plaintiffs Sherr-Una Booker, Lisa Hyde, Doris Jones, Carol Kruse, and Debra Mulkey. In moving to exclude Dr. Hurst's opinions, Defendants cite to his reports in the Mulkey, Jones, and Hyde cases. Docs. 7306, 7306-4, 7306-5.

gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Higher Complication Rates and "Unacceptable Risk" of Migration.

Dr. Hurst is a full time physician who received fellowship training in the field of interventional radiology at the University of Michigan Medical Center. Doc. 7306 at 4, 23. He has been the chief of vascular and interventional radiology for St. Elizabeth Health System in northern Kentucky for nearly 15 years, and serves the greater Cincinnati area through his private medical practice. *Id.* He is board certified in both general diagnostic radiology and specialized interventional radiology. *Id.* at 25. He regularly implants and removes IVC filters as part of his clinical practice, including filters manufactured by Bard. *Id.* at 4. He states that he is familiar with the medical literature concerning IVC filter issues, including filter complications and the risks and benefits associated with the devices. *Id.*

In each bellwether case, Dr. Hurst opines that Bard failed to notify the implanting physician of the "higher complication rates associated with the Recovery, G2, and Eclipse filters in comparison to the original predicate device, the Simon Nitinol Filter, and competitor filters." *See, e.g.*, Doc 7306 at 10. Dr. Hurst also opines that "Bard's own internal risk analysis deemed the G2 filter . . . to pose an 'unacceptable risk' of caudal migration." *Id.* at 11. Defendants contend that Dr. Hurst is not qualified to opine that their filters had higher complication rates than other filters or posed an "unacceptable risk" of caudal migration. Doc. 7302 at 4-7.

The Court concludes that the admissibility of such testimony will depend on the manner in which it is given. Dr. Hurst's reports state that physicians reasonably expect medical device manufacturers such as Bard to design, test, manufacture, warn, and

market in a manner that will enable the physicians to select appropriate IVC filters and make correct therapeutic decisions. Doc. 7306 at 8. He states that patients reasonably expect sufficient information to make an informed decision. *Id.* Dr. Hurst quotes the AMA Code of Medical Ethics on informed consent to support these assertions. *Id.* at 9. As an experienced interventional radiologist with years of practice, Dr. Hurst clearly is qualified to opine about the information physicians and patients need and expect when making decisions about the use of IVC filters.

But the precise intent of Dr. Hurst's statement that "Bard failed to notify operating physicians and the implanted patients of the much higher complication rates associated" with its filters (*id.* at 10), and that the G2 filter posed an "unacceptable risk" of caudal migration (*id.* at 11), is not clear. He could be stating that he has learned from other sources that Bard filters have higher complication rates and unacceptable risks of caudal migration, and, in his opinion as a practicing interventional radiologist, these facts, if true, should have been disclosed by Defendants. Such an opinion would fall within the area of his expertise and would be based on his years of experience as a physician, and would be admissible under Rule 702.

Alternatively, Dr. Hurst could be opining that Bard filters have higher complication rates than other IVC filters and have unacceptable risks of caudal migration. The Court is not persuaded that such an opinion would be admissible under Rule 702.

1. Higher Complication Rates.

Dr. Hurst has not conducted any study of IVC filter complication rates. He states that his opinions are based on personal experience with IVC filters, in combination with his "education and training in the field of medicine, and specifically the field of Vascular and Interventional Radiology[.]" Doc. 7306 at 4. But he does not state that he has collected clinical data from his personal cases that reveal IVC filter complication rates, nor that his education and training revealed anything about such rates. He also states that his opinion is "based on discussions with other physicians in [his] region and area, attendance at national meetings and discussions that were ongoing at the time as well[.]"

Doc. 7811 at 5 (quoting Ex. 2 at 52:12-24). But he cites no studies or data that were addressed in these discussions or meetings.

In short, Dr. Hurst provides no information from which the Court can conclude that his own experiences or training as a physician, or his own discussions with other doctors, provide "sufficient facts and data" to support an opinion on Bard filter complication rates. Fed. R. Evid. 702(b). Nor has he identified any "reliable principles and methods" he used in forming opinions from these sources. *Id.*, 702(c).

Dr. Hurst did testify that he reviewed a number of medical articles regarding IVC filter complication rates, and he focused particularly on the Deso article, which conducted a literature search regarding complications associated with various IVC filter designs. Doc. 7302-2.[3] But even if these articles suggest that Bard filters have higher complication rates than other filters, Dr. Hurst does not claim to have taken any steps to verify their conclusions, and merely restating those conclusions does not constitute a reliable basis for rendering an expert opinion under Rule 702. Dr. Hurst cannot simply repeat the opinions of others as his own when he has done nothing to verify the accuracy of the opinions. *See In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016) ("[The expert's] opinions . . . do not rely 'in part' on the purported expertise of other testifying experts. Rather, [the expert] repeats and concurs with their opinions, without additional analysis. The Court does not need an expert to reiterate other experts' testimony.").

2. Unacceptable Risk.

The opinion that the G2 filter poses an "unacceptable risk" of caudal migration is based on a Bard internal document, as Dr. Hurst notes. *See* Doc 7306 at 11. A report titled "G2 Caudal Migration Update" prepared by Bard product quality engineer Natalie Wong states that in certain circumstances the G2 filter had an "[u]nacceptable risk" of caudal migration per Bard's failure modes and effects analysis. *See* Doc. 7825 at 21.

[3] The article is "Evidence-Based Evaluation of [IVC] Filter Complications Based on Filter Type," co-authored by Drs. Steven Deso, Ibrahim Idakoji, and William Kuo, and published in *Seminars in Interventional Radiology* (Vol. 33 at 93-100, No. 2/2016).

Dr. Hurst has testified that he relied in part on the "Wong evaluation of the G2 caudal migration from the [Bard] internal documents." Doc. 7306-1 at 4-5 (Dep. Tr. 254:24-255:1).

Again, however, Dr. Hurst does not identify any steps he has taken to verify the conclusion in the Wong report. Nor does he identify the person or entity to whom the risk he mentions is unacceptable – physicians, patients, medical manufacturers, or the FDA. Dr. Hurst could opine, as a treating physician who must make decisions about IVC filter use, that Bard should have disclosed any risks it found in its products that would be unacceptable to doctors and patients. But he cannot opine that Bard filters present an unacceptable risk unless that opinion is based on sufficient facts and data he has identified, to which he has applied reliable principles and methods. Fed. R. Evid. 702(b), (c). Merely repeating conclusions of the Wong report as his own opinion does not meet this requirement.

3. Conclusion.

Dr. Hurst can testify that if Bard IVC filters had higher complication rates and unacceptable risks of caudal migration, then, in his opinion as a practicing interventional radiologist, those facts should have been disclosed by Defendants. But he cannot present an expert opinion that Bard IVC filters did in fact have higher complication rates and unacceptable risks of caudal migration without satisfying the reliability requirements of Rule 702. He has not done so in his report or deposition testimony.

B. Safety Signals, Additional Studies, and Representations About Filters.

Dr. Hurst renders several opinions about what Bard knew, did, or failed to do. He opines, for example, that Bard ignored early safety signals, chose not to perform additional studies, and falsely represented improvements in newer generation filters in its marketing materials. Doc. 7302 at 7-8; *see* Doc. 7306 at 10-12 (Opinions 4(d)(ii), (v), and (vi)).

The Court is not persuaded that Dr. Hurst is qualified to opine about Bard's internal knowledge, its internal testing and development practices, or the truthfulness of

its representations as a general matter. Plaintiffs do not suggest that Dr. Hurst has ever worked for a medical product manufacturer or the FDA, that he has expertise in internal corporate information gathering or decision making, or that he is trained in the design, testing, or labeling of medical devices. Plaintiffs have identified no basis upon which Dr. Hurst can render expert opinions about what happened internally at Bard – what it knew, what it did, or what it failed to do in the development and marketing of its IVC filters. Nor have Plaintiffs shown that Dr. Hurst had sufficient facts or data to form reliable opinions about the inner workings at Bard. As Defendants note, he reviewed only 24 internal Bard emails and documents.

As a practicing interventional radiologist, Dr. Hurst can testify about what a physician would expect to receive from Bard. But he cannot state opinions about what was known within Bard or what was or was not done within Bard. Such opinions are outside the realm of his expertise and are not supported by sufficient facts and data or evaluated through reliable principles and methods. Fed. R. Evid. 702(b), (c).

C. Bard's Lack of Communications Regarding the Meridian Filter.

Defendants ask the Court to preclude Dr. Hurst from opining that Bard failed to communicate to the implanting physicians in the Mulkey, Jones, and Hyde cases that the Meridian filter should be used instead of the Eclipse or G2X filters. Doc. 7302 at 10 (citing Doc. 7306 at 11-12). Plaintiffs agree that Dr. Hurst can render no such opinion in the Jones and Hyde cases because the Meridian filter was not on the market when these plaintiffs received their Bard filter implants. Doc. 7811 at 2, 9 n.2.

With respect to the Mulkey case, Defendants argue that Dr. Hurst's opinion is speculative because he does not know what information Bard provided to Mulkey's implanting physician or how the Meridian filter compares clinically to the Eclipse. Docs. 7302 at 10-11; 8223 at 7. This argument appears to be well taken. In addition to the fact that Dr. Hurst does not know what information Mulkey's physician received, Dr. Hurst has never implanted a Meridian filter and he identifies no study or data to suggest that the Meridian has fewer complications than the Eclipse. The Court

concludes, however, that a final ruling on this issue should await trial in the Mulkey case. The Court will then have the benefit of earlier bellwether trials and possibly testimony from Dr. Hurst himself.

D. Reasonable Expectations and Informed Consent.

Defendants' motion does not seek to exclude Dr. Hurst's opinions regarding what reasonable physicians and patients expect from medical device manufacturers, or his opinions about how the duty of informed consent bears on these expectations. Plaintiffs nevertheless argue in their response that these opinions will assist the jury. Doc. 7811 at 10. In their reply, Defendants disagree and argue that these opinions are inadmissible.

The Court will not grant relief on an argument not made in Defendants' motion, but because the issue has been addressed by the parties and will be relevant at trial, the Court confirms the views set forth above. Dr. Hurst's training and years of experience as an interventional radiologist qualifies him to opine on these subjects. Although a final decision must await trial, the Court also concludes that such testimony likely will be relevant to the jury's consideration of whether Defendants failed to warn Plaintiffs and whether that failure caused Plaintiffs' injuries.

IT IS ORDERED that Defendants' motion to exclude the opinions of Dr. Darren Hurst (Doc. 7302) is **granted in part and denied in part**. The motion is granted as follows: Dr. Hurst cannot (1) opine that Bard filters have higher complication rates than other IVC filters and have unacceptable risks of caudal migration, or (2) render opinions about Bard's internal knowledge, its internal testing and development practices, or the truthfulness of its representations in general.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Rebecca Betensky, Ph.D. Doc. 7288. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. IVC filters, such as Bard's Simon Nitinol Filter ("SNF"), originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters. Bard first marketed a retrievable filter in 2003. Seven different versions of Bard retrievable filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard retrievable filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that the filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

Plaintiffs have identified Dr. Betensky, a biostatistician, as an expert witness regarding risk rates associated with Bard filters. Dr. Betensky is the director of biostatistics programs at Massachusetts General Hospital and Harvard University. She is a faculty member at the Harvard-MIT Division of Health Sciences and Technology, has taught courses in biostatistics at Harvard School of Public Health, and has authored more than 200 peer-reviewed articles related to biostatistics. *See* Doc. 7818 at 4 n.4.

In this MDL, Dr. Betensky opines generally that there is a higher risk of adverse events for Bard's retrievable IVC filters than for its permanent SNF. Doc. 7290. Dr. Betensky relied on sales information provided by Bard and adverse event reports extracted from the MAUDE database maintained by the Food and Drug Administration ("FDA").[1] Dr. Betensky compared, over multiple time periods, the proportion of adverse event reports for each Bard retrievable filter relative to sales, to the proportion of adverse event reports for the SNF over sales. *Id.* at 2. She calculated a "reporting risk ratio" ("RRR") as the ratio of the reporting risk for each retrievable filter to that of the SNF,

[1] The MAUDE database houses adverse event reports submitted to the FDA by medical device manufacturers, hospitals and healthcare professionals, and patients and consumers. *See FDA, MAUDE – Manufacture and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last updated Dec. 31, 2017; last visited Jan. 16, 2018). Reporting by patients and consumers is voluntary, but manufacturers and hospitals must submit reports when they become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury. *See id.*

using this equation: RRR = $(x_1/n_1)/(x_2/n_2)$.[2] The RRR is then used as an estimate of the actual risk ratio ("RR") for the various filters. An RRR value larger than 1 suggests a higher RR for the retrievable filters than for the SNF. *Id.* at 4. Dr. Betensky found that for each Bard retrievable filter, there were statistically significant increased RRRs for adverse events such as death due to filter embolization and filter fracture, migration, perforation, or tilt. *Id.* at 3, 8-12, 15.

Defendants challenge Dr. Betensky's opinions on several grounds. Defendants contend that she applied unfounded assumptions in her calculations, resulting in biased opinions that may not reflect an actual increased risk for retrievable filters. Defendants further contend that the opinions are flawed because Dr. Betensky failed to consider potential adverse events from the first ten years the SNF was on the market, or rule out alternative explanations for the increased risk she estimated. Finally, Defendants contend that the opinions are based solely on an improper comparison of anecdotal adverse event reports contrary to express guidance from the FDA. Doc. 7288 at 2.[3] Plaintiffs oppose the motion, arguing that Dr. Betensky is a highly-qualified expert who considered all available data and used a reliable methodology to form her opinions. Doc. 7818. For reasons stated below, the Court finds that Defendants' criticisms, to the extent valid, go the weight to be afforded the opinions, not their admissibility.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods

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[2] In the equation, x_1 and n_1 denote, respectively, the number of adverse event reports and sales for the retrievable filter, while x_2 and n_2 denote the same information for the SNF.

[3] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Assumptions About Adverse Event Reporting.

Dr. Betensky's expert report acknowledges and discusses potential limitations in her analysis. Doc. 7290 at 12-14. These include the possibility that adverse events were underreported for one or more of the devices at issue. Dr. Betensky found that while the RRRs she calculated may involve some degree of underreporting, which makes them "imperfect estimates of the actual risk ratios," there is strong evidence that actual risk ratios are higher for Bard retrievable filters than for the SNF. *Id.* at 13. Dr. Betensky explained her reasoning as follows:

> [A]dverse events are generally considered to be underreported to the databases, and potentially differentially by severity of adverse event and by drug or medical device. . . . It is important to recognize that underreporting in and of itself is not problematic. Rather, differential underreporting of the higher risk device is what leads to bias. And even if there was differential underreporting of the higher risk device, given the variation in reporting relative risks across adverse events, the differential reporting would have had to have been highly variable across adverse events. This does not seem plausible given the severity of the adverse events considered. Given the magnitude of the RRR's, and their variability across adverse events, it seems implausible that differential underreporting by filter could fully explain the deviation of the observed RRR's from 1.

Id. at 12. Dr. Betensky further explained that if Bard "believed that there truly was no elevation in risk associated with Recovery due to SNF, but that all of the signals of elevated reporting risk were due to differential underreporting, it seems likely that they would have increased their monitoring and corrected this problem, especially if underreporting of SNF were due to decreased detection due to its permanence." *Id.* at 13.

Dr. Betensky considered and addressed the possible influence of the Weber effect, which results from increased reporting soon after the launch of a new drug or device. *Id.* at 14. She concluded that the Weber effect does not appear to be at work in the data she analyzed because "the RRR's mostly increase over time." *Id.*

Dr. Betensky further considered whether the incidence of adverse event reporting could have been influenced by publicity, a phenomenon known as the "notoriety effect" or "stimulated reporting." *Id.* She found that the only possible cause of such an effect would be an FDA warning letter about Bard filters, but concluded that the letter did not affect the data she used because the letter was issued in 2015 and the data she used ended in 2014. *Id.* at 2, 14.

Defendants argue that Dr. Betensky's assumptions about adverse event reporting are unreliable because she is not a doctor or an expert in any scientific field other than statistics, and did not collaborate with a medical expert. Doc. 7288 at 8-11. Defendants base this argument on the following assertion: "Determining whether or not assumptions about detection and reporting of adverse events in retrievable and permanent filters are 'plausible' requires an expert understanding of these complex medical devices and their uses." *Id.* at 8. But Defendants provide no citation for this assertion – from their own statistical expert, medical literature, or case law – and it is not apparent to the Court that the assertion is correct.

Dr. Betensky is a highly trained and qualified expert in *bio*statistics, and, as she testified, has "25 years of experience as a Ph.D.-level statistician who has collaborated extensively with investigators in the medical field." *Id.* at 9. The Court cannot conclude that she is unqualified to make reasonable assumptions in her statistical analyses. Dr.

Betensky explained her assumptions, acknowledged their shortcomings, and engaged in sensitivity and other statistical inquiries to test their validity. Doc. 7290 at 12-15. Her opinions are not, as Defendants assert, based solely on "her *ipse dixit*." *Id.* at 2, 11 (citing *G.E. v. Joiner*, 522 U.S. 136, 146 (1997)). This "is not a case where 'there is simply too great an analytical gap between the data and the opinion proffered.'" *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489793, at *7 (S.D. Fla. Feb. 24, 2010) (quoting *Joiner*, 522 U.S. at 146). If Defendants believe Dr. Betensky's assumptions are incorrect (Doc. 7288-3 at 11-12), they can make that assertion through their own statistical expert, Dr. Ronald Thisted (Doc. 8175-4), and can cross examine Dr. Betensky.

Each side has presented a highly qualified statistical expert to opine on the available data about Bard IVC filter failure rates. Dr. Betensky readily acknowledges the assumptions used in her analysis and explains why she believes they are reasonable. She also acknowledges the shortcomings in available data, and admits that she can develop only an estimate of filter risks. But she explains carefully why she believes her estimates are reliable, using statistical techniques to test the estimates and her assumptions. Bard's expert, Dr. Thisted, reaches different conclusions, and carefully explains why.

The Court concludes that this testimony, from two well-qualified experts in statistics, addressing the only data available on comparative risk rates of Bard IVC filters, is sufficiently reliable to satisfy Rule 702 and *Daubert*. "It is not the job of the court to insure that the evidence heard by the jury is error-free," but to insure that it is sufficiently reliable to be considered by the jury. *Southwire Co. v. J.P. Morgan Chase & Co.*, 528 F. Supp. 2d 908, 928 (W.D. Wis. 2007); *see Trasylol*, 2010 WL 1489793, at *7 (the court "must be careful not to conflate questions of admissibility of expert testimony with the weight appropriately to be accorded to such testimony by the fact finder"). Applying the factors identified in Rule 702, the Court finds that Dr. Betensky's evidence meets this standard. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014, 1997

WL 230818, at *8 (E.D. Pa. May 5, 1997) (noting that "there is no such thing as a perfect epidemiological study"); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 1230, 1240 (W.D. Wash. 2003) ("Because the court finds the methodology scientifically sound, any flaws that might exist go to the weight afforded the [study], not its admissibility.").

B. Adverse Events for the SNF and Alternative Explanations.

Defendants argue that Dr. Betensky's analysis is fatally flawed because she considered adverse event reports and sales data for each retrievable filter starting at product launch, but considered no data for the first ten years the SNF was on the market (1990-2000). Doc. 7288 at 11. This omission is particularly egregious, Defendants contend, given that, under the Weber effect, increased reporting can be observed soon after product launch. *Id.* at 11-12. Defendants claim that had Dr. Betensky considered the missing data, she may not have estimated any increased risk in reporting for retrievable filters. *Id.* at 12. Defendants also argue that Dr. Betensky failed to account for differences between retrievable filters and the SNF in terms of detecting asymptomatic adverse events. *Id.* at 12-13.

Defendants argue that pre-2000 SNF data were available to Dr. Betensky on specific spreadsheets Defendants produced to Plaintiffs. Doc. 8221 at 5-6. Significantly, however, Defendants make no attempt to show that the data would have altered Dr. Betensky's conclusions. They make no calculations with the data. Defendants speak only in terms of possibilities, asserting that it is "entirely possible" that data from the first decade of SNF would have altered her conclusions. Docs. 7288 at 12, 8221 at 3. The Court cannot conclude that Dr. Betensky's opinions are unreliable on the basis of mere possibilities. The Court agrees with Plaintiffs that this argument is suitable for cross examination at trial, not for exclusion under Rule 702. Doc. 7818 at 14.

C. Anecdotal Adverse Event Reports.

Defendants contend that Dr. Betensky's opinions are inadmissible because they are based on anecdotal adverse event reports that were made either directly to Bard or

that Bard retrieved from the MAUDE database. Doc. 7288 at 13. Reliance on MAUDE data is problematic, Defendants claim, because the "database is a 'passive surveillance system [that] has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data.'" *Id.* at 13-14; *see* Doc. 288-5 at 2. Defendants note that the FDA itself has cautioned that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices" (Doc. 7288-4 at 2), and has suggested, in the context of pharmaceutical drugs, that "comparison of two or more reporting rates be viewed with extreme caution" (Doc. 7288-6 at 15). *Id.* at 15-16.

Plaintiffs counter that Dr. Betensky did not use MAUDE data, but relied instead on Bard's own internal adverse event and sales data which Bard witnesses have confirmed to be complete, accurate, and reliable. Doc. 7818 at 5-7. Plaintiffs also note that Bard relies on the same data, the FDA recommends that manufacturers use such data to conduct reporting rate analyses, and implanting physicians have published similar analyses of IVC filters. *Id.* at 4-10. Plaintiffs also assert that other lines of evidence support Dr. Betensky's opinion that there is a higher risk of adverse events for Bard's retrievable IVC filters than for the SNF. *Id.* at 10-12.

The Court is persuaded by Plaintiffs' arguments. Dr. Betensky used the only available evidence on Bard filter failure rates – evidence that Bard compiled internally and through MAUDE, and that Bard used internally to make failure rate comparisons. Of course, the fact that this is the only available evidence does not mean that opinions based on it must be admitted; unreliable evidence should not be admitted solely because other evidence cannot be obtained. But Dr. Betensky readily concedes the limitations in the data she used and openly confirms that she has developed an estimate of failure rates, not completely accurate failure rates. She explains, as an expert biostatistician, why her estimates nonetheless reliably suggest that Bard's retrievable filters fail more often than the SNF.

The Court cannot conclude that statisticians should be permitted to testify only when they can derive rock-solid truth. In fact, statisticians would not been needed if such truth was discernable. Statisticians deal in probabilities, trends, and mathematically supported inferences. The Court finds that Dr. Betensky is eminently qualified to provide such opinions, that she does not overstate her findings, that she clearly explains the basis for her assumptions and conclusions, and that the jury should be permitted to hear and evaluate her opinions in light of Defendants' criticisms and counter-expert.

"Under *Daubert*, an expert need not base his or her opinion on the best possible evidence, regardless of availability, but upon 'good grounds based on what is known.'" *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 178 (S.D.N.Y. 2009) (quoting *Daubert*, 509 U.S. at 590). And *Daubert* makes clear that "disputes about the facts underlying an expert's opinions are best addressed through the adversarial process and then by the jury as the ultimate fact-finder." *In re Levaquin Prods. Liab. Litig.*, MDL No. 08-1943 (JRT), 2010 WL 8399942, at *11 (D. Minn. Nov. 4, 2010) (citing *Daubert*, 509 U.S. at 595-96).

Defendants cite *In re Accutane Products Liability Litigation*, 511 F. Supp. 2d 1288, 1298 (M.D. Fla. 2007), which found an expert's reliance on adverse event reports "unreliable as proof of causation because, in general, the events were not observed in such a way as to rule out coincidence or other potential causes." But Dr. Betensky does not present a causation opinion.[4]

[4] The other cases cited by Defendants address either causation opinions or those based on clearly unreliable evidence. *See Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) (anecdotal case reports of patients suffering injuries after taking prescription drug "did not by themselves provide reliable proof of causation"); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) (finding anecdotal studies used to support medical causation unreliable "in the face of controlled, population-based epidemiological studies which find otherwise"); *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1165 (S.D. Fla. 1996) (excluding causation opinion of pharmacologist who "did not rely on the actual case reports, but only on secondary authorities summarizing the primary clinical findings"); *In re Denture Cream Prods. Liab. Litig.*, No. 09-2051-MD, 2015 WL 392021, at *24 (S.D. Fla. Jan. 28, 2015) (finding the expert's summary of a collection of case reports unreliable where it involved "layers of unsupportable estimations and approximations added to [an] already shaky foundation").

Other courts have noted that adverse event reports, including reports from the MAUDE database, may be used for opinions other than causation. *See Tillman v. C. R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1332 (M.D. Fla. 2015) (allowing opinion in Bard IVC filter case based on MAUDE data); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *11 (N.D. Ohio May 4, 2010) (allowing expert testimony based in part on adverse event reports where the reports were relied on by the FDA in reviewing relative risk, and noting that the defendant was "free to cross-examine the . . . experts regarding the flaws in adverse event reporting"); *Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2015 WL 7888387, at *5-7 (S.D. Ohio Dec. 4, 2015) (considering on summary judgment expert testimony based in part on MAUDE data where the expert acknowledged that there are limitations to the data); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 2436, 2016 WL 3854534, at *26 (E.D. Pa. July 14, 2016) ("No study is perfect nor every piece of data entirely accurate. Any flaws in the [expert's] analysis should be brought out on cross-examination[.]").[5]

IT IS ORDERED that Defendants' motion to exclude the opinions of Rebecca Betensky, Ph.D (Doc. 7288) is **denied**.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge

[5] Because Defendants will have a full opportunity to cross examine Dr. Betensky and present their own statistical expert, the Court does not agree that admitting Dr. Betensky's opinions will be unfairly prejudicial under Rule 403. Doc. 7288 at 17.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Plaintiffs have filed a motion to exclude the opinions of Dr. Clement Grassi. Doc. 7326. Defendants have filed a response. Doc. 7798. No reply has been filed, and the parties agree that oral argument is not necessary. The Court will deny the motion as moot.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. Like most medical devices on the market today, the Bard IVC filters at issue in this MDL received premarket clearance from the Food and Drug Administration ("FDA").

Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to neighboring organs. Plaintiffs further allege that Bard failed to warn physicians and patients about these higher risks. Doc. 303-1. Bard disputes Plaintiffs' allegations,

contending that complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

Defendants have identified Dr. Grassi, an interventional radiologist, as an expert witness on various issues related to Bard IVC filters. Plaintiffs do not dispute Dr. Grassi's expertise in the field of interventional radiology, but contend that he is not qualified to offer opinions about the FDA regulatory process for IVC filters. Doc. 7326 at 3-5. Plaintiffs identify no such opinions in Dr. Grassi's expert report. Instead, Plaintiffs seek to exclude Dr. Grassi's deposition testimony that (1) he "know[s] from personal experience when [he] participated in the Simon nitinol FDA pre-approval testing what was done in terms of testing with that filter device" (Doc. 7798-2 at 5), and (2) he is "aware of the processes and the standards that [Bard] is required to undergo as part of its FDA pre-acceptance testing under what would be a 510(k) application" (Doc. 7326-2 at 4).

Defendants respond that Dr. Grassi does not purport to be an FDA regulatory expert, and that he will limit his opinions at trial to the issues addressed in his report. Doc. 7798 at 3-4. Given this avowal, Plaintiffs' motion to exclude Dr. Grassi's deposition testimony is moot.

IT IS ORDERED that Plaintiffs' motion to exclude the opinions of Clement Grassi, M.D. (Doc. 7326) is **denied** as moot.

Dated this 6th day of February, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Robert McMeeking, Ph.D. Doc. 7314. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. IVC filters, such as Bard's Simon Nitinol Filter ("SNF"), originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters.

Bard retrievable filters are spider-shaped devices with multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC wall, and shorter curved arms that serve to catch or break up blood clots. Seven different

versions of Bard filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. Each of these filters is a variation of its predecessor. Bard first obtained Food and Drug Administration ("FDA") clearance to market the Recovery in 2003. The last-generation Denali received FDA clearance in 2013.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs, among other things, allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that Bard filters are not defective and their overall complication rates are comparable to those of other IVC filters.

Plaintiffs have identified Dr. McMeeking, a mechanical engineer and materials scientist, as an expert witness on the design of Bard filters. Dr. McMeeking received his master's and doctorate degrees from Brown University. He currently teaches at the University of California, Santa Barbara, as a distinguished professor of structural materials and mechanical engineering, and has taught in these fields for more than 40 years. He is a member of prestigious engineering societies, has published peer-reviewed articles and served as an editor for engineering journals, and has received awards and honors for his work in the field of mechanical engineering. With respect to medical devices, Dr. McMeeking has testified before the FDA on device design and testing issues, and has served as a consultant to leading manufacturers of medical implants. Doc. 7318 at 3, 125-63.[1]

Dr. McMeeking has authored a report assessing design aspects of Bard filters. *Id.* at 1-175. The report provides Dr. McMeeking's credentials and a description of the methodology he employed, and sets forth objective industry and engineering standards

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

for the design of medical implants. *Id.* at 3-10. The report contains a preliminary description of each Bard filter (*id.* at 10-28), and a more detailed assessment of the design, mechanical behavior, and stress and strain characteristics of the Recovery and G2 (*id.* at 28-83). The detailed assessment includes, among other things, a discussion of Bard's *in vivo* loading and finite element analyses, its testing protocols, expected filter strains and their effects on reliability, the impact of device geometry and fabrication, and the risk of filter fracture, migration, perforation, and tilt. The report concludes with a list of documents reviewed, references, and figures and diagrams. *Id.* at 81-124.

Defendants do not challenge Dr. McMeeking's qualifications to opine about design aspects of Bard filters from an engineering perspective, nor do they seek to exclude his opinions that the filters are defective in various ways. Rather, Defendants ask the Court to exclude several categories of opinions: (1) Bard did not go far enough to reduce filter risks; (2) Bard failed to fully communicate relevant information to the FDA; (3) the complication rates for Bard retrievable filters are "dangerous"; and (4) the SNF is a safer, alternative device. Doc. 7314 at 2. The Court will address each category.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Bard Did Not Go Far Enough to Reduce Filter Risks.

Defendants ask the Court to exclude Dr. McMeeking's opinion that Bard failed to "eliminate risks as far as reasonably practicable through inherently safe design and manufacture[.]" Doc. 7318 at 7. In support of this argument, however, Defendants do not cite to Dr. McMeeking's 82-page, single-spaced report, nor to his 16-page rebuttal report. *See* Docs. 7318, 7318-4. Defendants instead cite only to his deposition, to show both that he holds the opinion Defendants seek to exclude and that he lacks a reliable basis for it. Doc. 7314 at 4-7. Reading the motion provides the Court with no indication of what portions of Dr. McMeeking's lengthy report or rebuttal report Defendants seek to exclude. And Defendants' reply provides no additional help – it contains three pages of block quotes from Dr. McMeeking's deposition and not one citation to his reports. Doc. 8227 at 2-6.

Unfortunately, Plaintiffs' response is not much help either. Plaintiffs accuse Defendants of "cherry pick[ing]" language from Dr. McMeeking's deposition testimony, but they do not state whether they plan to present the specific opinion Defendants identify from the deposition, nor do they reveal its location in his report or the complete basis for it. Doc. 7806 at 8-10. Plaintiffs do assert that the report identifies proposed design changes Bard could have made, but they cite only two examples: eliminating strain concentration and fretting of limbs. *Id.* at 7. Plaintiffs also note that Dr. McMeeking found Bard's design process to be deficient because they did not duplicate past failures or consider worst-case scenarios. *Id.* at 7. Plaintiffs contend generally that his opinions are reliable because they are based on his quantitative and finite element analyses, mathematical calculations, and a review of Bard's testing data and other engineering documents. *Id.* at 6, 11.

Having read the briefs, more than once, the Court cannot determine precisely what opinions in the reports Defendants seek to exclude, whether Plaintiffs even intend to present the opinion Defendants cite from the deposition, and, if so, where that opinion is

supported in the reports. The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony admissible, but Defendants have the burden of at least identifying the opinions Plaintiffs must defend in a *Daubert* motion. Given the state of the parties' briefing, the Court cannot conclude that portions of the planned McMeeking testimony should be excluded.

Dr. McMeeking's report does identify the following general principle for the safety and performance of medical devices:

> The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; *eliminate risks as far as reasonably practicable through inherently safe design and manufacture*; reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and inform users of any residual risks.

Doc. 7318 at 7 (emphasis added). Elsewhere in his report, Dr. McMeeking states that Bard failed to apply this and other standards, grouping all of the violated standards together in a single sentence. *Id.* at 12, 17, 22, 27. Each of these statements is made in the context of Dr. McMeeking's discussion of a specific generation of Bard IVC filters and its defects. The Court cannot tell what exactly Plaintiffs intend to elicit on this subject at trial, and the parties' briefs largely fail to discuss the statements in their contexts in the report. Objections will have to be resolved at trial.

Dr. McMeeking's report does identify certain alleged design defects, including strain concentrations causing rapid limb fatigue and fracture, the unstable manner in which the filter head holds the limbs in place, the instability of the filter in the IVC leading to tilt and perforation, and the small diameter of the filter limbs causing perforation. Doc. 7318 at 11-12. These alleged defects lead Dr. McMeeking to conclude that the G2 was not thoroughly tested, that attempts to identify all possible failure modes

were inadequate, and that Bard did not use strain-analytical methods. *Id.* Some of these opinions are close to the opinion Defendants seek to exclude, but Defendants say nothing about the reasoning provided for these opinions in Dr. McMeeking's report, and the Court cannot conclude from somewhat unconnected deposition answers that they should be excluded. Again, the Court will rule on specific objections at trial.

B. Bard Failed to Fully Communicate Relevant Information to the FDA.

Dr. McMeeking states in his report that Bard was not "frank and honest" with the FDA in that the company "did not fully inform the FDA of deficiencies that the G2 filter was exhibiting after implant." Doc. 7318 at 12, 18. He clarified during his deposition that while he is not offering an opinion as to whether Bard's corporate behavior met the FDA's expectations, "in a couple of situations, [he] identified information that Bard gave to the FDA which was not correct[.]" Doc. 7318 at 17-18.

Defendants concede that Dr. McMeeking is qualified to opine that certain Bard documents provided to the FDA contain technical inaccuracies. Docs. 7314 at 7, 8227 at 7. They argue, however, that the opinion that Bard was not "frank and honest" with the FDA should be excluded because Dr. McMeeking is not qualified to offer the opinion and has identified no reliable methodology. Doc. 7314 at 7-8. The Court agrees.

Dr. McMeeking has testified before the FDA based on his knowledge and experience as a mechanical engineer and materials scientist (Doc. 7318 at 3), but this does not make him an FDA regulatory expert. He has identified no other expertise or specialized knowledge that enables him to opine on what the FDA requires of IVC filter manufacturers. And he does not purport to know the full context and content of Bard's communications with the FDA, or the company's intent behind any communication.

Plaintiffs note that Dr. McMeeking relies on the opinions of Dr. Parisian, and contend that an expert's opinions may be based on the reliable opinions of other experts. Doc. 7806 at 12-13. But Dr. McMeeking cannot merely act as a conduit for Dr. Parisian's opinions regarding Bard's communications with the FDA. *See* Doc. 9771 at 5; *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods.*

Liab. Litig., 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013). His report and testimony suggest he is doing just that. He states that Bard's failure to be "frank and honest" with the FDA "[has] been documented by Parisian, where further details are to be found." Docs. 7318 at 12. And when asked about the opinion during his deposition, he stated: "The basis, I'm relying on Dr. Parisian for that opinion." 7318-1 at 17. As the Court previously has held, an expert cannot simply repeat the opinions of other experts as his own when he has done nothing to verify the accuracy of the opinions. Doc. 9772 at 5; *see In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016) ("[The expert's] opinions . . . do not rely 'in part' on the purported expertise of other testifying experts. Rather, [the expert] repeats and concurs with their opinions, without additional analysis. The Court does not need an expert to reiterate other experts' testimony.").

The Court will exclude Dr. McMeeking's opinion that Bard was not "frank and honest" with the FDA. Dr. McMeeking may, however, opine from an engineering perspective that certain information Bard provided to the FDA is not correct.

C. Filter Complication Rates Are Dangerous.

Dr. McMeeking states in his report that he has reviewed Dr. Betensky's analysis of adverse event reporting and finds the analysis to be consistent with and supportive of his engineering-based opinions. Doc. 7318 at 27-28. Dr. McMeeking stated during his deposition that he will offer no opinion on the relative rates of filter complications. Doc. 7318-1 at 29. When asked about opinions regarding the medical literature, he stated:

> I'm not going to give opinions on what's in the medical literature, other than to say that they're consistent with my assessment of the engineering considerations of the filter *and that they tend to confirm that the filters . . . are dangerous*.

Id. at 30 (emphasis added). Defendants note that it is unclear whether Dr. McMeeking intends to offer opinions about "dangerous" complication rates, and they seek a ruling from the Court excluding any such opinion. Doc. 7314 at 9-11 & n.2.

Plaintiffs make clear in their response that Dr. McMeeking will offer no such opinion and that he relies on Dr. Betensky's report only to confirm the results of his own engineering analysis. Doc. 7806 at 14. The Court will accept this representation by Plaintiffs. Defendants may object if they believe Dr. McMeeking is rendering an opinion that Bard filters are dangerous.

D. The SNF is a Safer Alternative Filter.

Dr. McMeeking prepared a rebuttal report to several of Defendants' experts. Doc. 7318-4. He concludes the report as follows:

> Given my analysis as detailed above, I conclude from an engineering perspective that the design of the SNF is substantially better than those of the Recovery, G2 and similar Bard filters, with respect to migration, tilt, arm fracture and arm perforation, after considering the combination of attributes that are positive or negative in each case for each filter design. Therefore, based on my assessments it is my opinion that, in sum, the SNF is a safer filter than the Recovery, G2, and similar Bard filters.

Id. at 17.

Defendants contend that Dr. McMeeking should not be allowed to make the leap from evaluating the design characteristics of Bard filters to opining that the SNF is a safer device. Doc. 7314 at 12. Defendants cite cases applying a specific requirement of New York law – that a plaintiff in a design defect case prove the product was "not reasonably safe because there was a substantial likelihood of harm and *it was feasible to design the product in a safer manner*." *Voss v. Black & Decker Mfg. Co*., 450 N.E.2d 204, 208 (N.Y. 1983) (emphasis added). Defendants' cited cases, *McCarthy v. Olin Corp.*, 119 F.3d 148 (2d Cir. 1997), and *Felix v. Akzo Nobel Coatings*, 262 A.D.2d 447 (N.Y. App. Div. 1999), held that the allegedly dangerous feature of the challenged product was in fact necessary to make the product function as intended, and that it was therefore not feasible to design the product in a safer manner. In *McCarthy*, the alleged defect – the expansion upon impact of hollow-point bullets – was an intentional element of the product's design. The court noted that "the very purpose of [hollow-point] bullets is to kill or cause severe wounding," and the bullets "performed precisely as intended[.]"

119 F.3d at 155. In *Felix*, the plaintiff's own expert admitted that the very nature of the quick-drying lacquer product "necessitated that it contain a highly flammable solvent," and that "nothing [could] be introduced to the formula to make it safer without creating an entirely different product." 262 A.D.2d at 448.

Defendants make no effort to show that the law governing the bellwether trials will impose the same requirement as New York law. Nor do they address whether the functional differences between the SNF and the retrievable filters in this case are so great that the retrievable filters could not feasibly be designed liked the SNF. (That may well be a subject for expert testimony, if such testimony has been disclosed.) As a result, the Court cannot conclude that Dr. McMeeking's safety comparison will be inadmissible in the bellwether trials.

In their reply brief, Defendants cite one case that applies Georgia law – the law to be applied in the first bellwether trial – but they do not discuss the case or Georgia law. Doc. 8227 at 11 (citing *Mascarenas v. Cooper Tire & Rubber Co.*, 643 F. Supp. 2d 1363, 1369 (S.D. Ga. 2009)). The case notes that Georgia applies a risk-utility analysis to design defect claims. The essential inquiry "is whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware." *Mascarenas*, 643 F. Supp. 2d at 1369 (quotation marks and citation omitted). Among a number of factors to be considered are "the state of the art at the time the product is manufactured" and "the ability to eliminate danger without impairing the usefulness of the product or making it too expensive." *Id.* "In general, weighing the risk-utility factors is a task left to the jury." *Id.* The Court cannot conclude from this law that Dr. McMeeking's opinion will be inadmissible in the first bellwether trial, particularly in the absence of arguments from the parties. His opinion that the SNF is safer may well be one factor for the jury to consider, along with Defendants' arguments that retrievable filters are functionally different from the SNF and therefore could not feasibly have been designed in the same way.

Defendants argue that Dr. McMeeking is not qualified to opine that the SNF would have been a safer alternative filter for any particular plaintiff, including the plaintiffs in the bellwether cases. Doc. 7314 at 13. Plaintiffs agree, and have made clear that Dr. McMeeking will offer no such opinion at trial. Doc. 7806 at 21.

Finally, Defendants object to Dr. McMeeking relying on Dr. Betensky's opinions that the SNF is a safer device. Doc. 7314 at 12. Contrary to Defendants' assertion, however, Dr. McMeeking's methodology is not mere "blind reliance" on Dr. Betensky's work. Doc. 8227 at 14. His opinion is based largely on his own independent engineering assessment of the SNF and the G2 and Recovery filters. Doc. 7318-4 at 9-17. He notes that his comparison of the filters "is in agreement with the adverse event reports." *Id.* at 9. That is not an improper adoption of Betensky's work.

The Court will not grant Defendants' request to preclude Dr. McMeeking from opining that the SNF is a safer device than Bard retrievable filters. But he may not opine that the SNF would have been a safer alternative for any particular plaintiff.[2]

IT IS ORDERED that Defendants' motion to exclude the opinions of Robert McMeeking, Ph.D. (Doc. 7314) is **granted in part** as set forth in this order.

Dated this 8th day of February, 2018.

David G. Campbell
United States District Judge

[2] Defendants also argue generally that the opinions of Dr. McMeeking challenged in their motion will not assist the jury, but they provide no explanation for this assertion. Doc. 7314 at 3.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Robert Ritchie, Ph.D. Doc. 7316. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. IVC filters, such as Bard's Simon Nitinol Filter ("SNF"), originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters.

Bard retrievable filters are spider-shaped devices with multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC wall, and shorter curved arms that serve to catch or break up blood clots. Seven different

versions of Bard retrievable filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. Each of these filters is a variation of its predecessor. Bard first obtained Food and Drug Administration ("FDA") clearance to market the Recovery in 2003. The last-generation Denali received FDA clearance in 2013.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs, among other things, allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that Bard filters are not defective and their overall complication rates are comparable to those of other IVC filters.

Plaintiffs have identified Dr. Ritchie, a mechanical engineer and materials scientist, as an expert witness on the design and manufacture of certain Bard filters. Dr. Ritchie received a bachelor's degree in physics and metallurgy, a master's degree in materials science, and a doctorate degree in materials science, all from Cambridge University. He has taught engineering courses at Massachusetts Institute of Technology, and currently teaches materials science as a distinguished professor at the University of California, Berkeley. He is a member of prestigious science and engineering academies, has published hundreds of peer-reviewed articles in the technical literature, and is highly regarded for his research in the fields of fatigue and fracture mechanics. With respect to medical devices, Dr. Ritchie has testified before the FDA about device fatigue and fracture and has served as a consultant to leading manufacturers of medical implants. Docs. 7319-1 at 3, 7319-2 at 49-50.[1]

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

Dr. Ritchie has authored a report assessing the structural integrity of Bard's G2, G2 Express, and Eclipse filters. He examined more than two dozen Bard filters that had experienced fractured limbs and other failures while implanted. Doc. 7319-1 at 3. He also reviewed internal Bard documents, medical records, medical and technical literature, other expert reports, and certain deposition testimony. *Id.* at 3-4. He opines that the fractures resulted from high cycle fatigue, which is the failure of a metal component over time due to cyclically varying physiological loading. *Id.* at 4, 25-30, 35-38. He further opines that contributing factors to the fatigue and resulting fractures include the lack of a chamfered filter head, poor surface conditions, rough grinding markings, and increased stress due to filter tilt and migration. *Id.*

Defendants do not challenge Dr. Ritchie's qualifications to opine about the manufacture and design of Bard filters from a technical perspective, nor do they seek to exclude his opinions about filter fatigue and fracture. Rather, Defendants ask the Court to exclude several categories of opinions: (1) Bard filters have "unacceptably high" complication rates; (2) one filter complication leads to others in a "vicious circle" of adverse events; (3) Bard's testing was insufficient; and (4) the SNF is a safer, alternative device. Doc. 7316 at 2. The Court will address each category.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the

task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Bard Filters Have "Unacceptably High" Complication Rates.

Dr. Ritchie opines in his report that Bard filters have "totally unacceptable failure rates." Docs. 7319-1 at 45, 7319-2 at 48. His rebuttal report states that the filters have an "unacceptably high incident of filter fractures." Doc. 7319-3 at 6. And he testified in his deposition that fracture rates are "particularly high" and "unacceptable." Doc. 7319 at 34. Defendants concede that Dr. Ritchie can testify about his own observations of filter fracture, but argue that any opinion about "high" or "unacceptable" complication rates should be excluded because Dr. Ritchie is not qualified to offer such opinions and has provided no reliable foundation for them. Doc. 7316 at 4-10. The Court agrees.

Dr. Ritchie's expertise is in the fields of mechanical engineering and materials science. He is not a medical doctor, biostatistician, or epidemiologist experienced in interpreting medical studies and data about device failure rates. Docs. 7319 at 43, 7319-4 at 4. And he has identified no other expertise or specialized knowledge that enables him to opine that Bard filters have unacceptably high complication rates.

Nor has Dr. Ritchie provided sufficient facts and data to support his opinions regarding filter complication rates, or identified any reliable principles and methods he used in forming such opinions. He testified that he read some small studies, but does not describe them or claim to have taken any steps to verify their conclusions. Doc. 7319 at 32-35. Plaintiffs themselves acknowledge that Dr. Ritchie's opinions "simply echo what is already reported in the literature." Doc. 7807 at 5. Dr. Ritchie stated that he uses the "unacceptably high" term "loosely" and only as a "personal statement" (Doc. 7319 at 33-34), and yet subjective personal beliefs are not appropriate expert opinions. *See Daubert*, 509 U.S. at 590 (noting that the word "knowledge" in Rule 702 "connotes more than subjective belief or unsupported speculation"); *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-1928, 2010 WL 1489793, at *8-9 (S.D. Fla. Feb. 24, 2010) (excluding

opinions under Rule 702 where they were based on subjective beliefs rather than any objective standard or specialized knowledge).

Plaintiffs note that Dr. Ritchie relies on Dr. Betensky's opinions, and contend that such reliance is permissible to the extent those opinions satisfy the *Daubert* requirements. Doc. 7807 at 5. But even if Dr. Betensky's opinions about adverse event rates are reliable, Dr. Ritchie has taken no steps to verify her work. Doc. 7319 at 41. He read Dr. Betensky's report and mentions it briefly in the introduction of his report (Doc. 7319-1 at 6), but he concedes that he does not discuss her analysis further or rely on it for his opinions (Doc. 7319 at 40). Plaintiffs fail to explain how Dr. Ritchie's expertise in engineering or materials science support an opinion that filter complication rates are too high, and he never identifies the person or entity for whom the rates are unacceptable – physicians, patients, manufacturers, or the FDA.

Dr. Ritchie will not be permitted to opine that Bard filters have "high" or "unacceptable" complication rates.

B. The "Vicious Circle" of Filter Complications.

Dr. Ritchie concludes his report with this opinion about the synergistic effect of filter failure modes:

> *The "Vicious Circle":* Finally, it should be recognized that many of these adverse events or modes of failure are coupled. For example, a "vicious circle" can be created by the rough grinding markings, not polished out by Bard in the ankle regions of the legs, which clearly can result in fatigue fractures of the feet; such a loss of one or more "anchors" of the filter can make the device far more prone to tilting and/or migration, which can change the stress states and/or promote the possibility of penetrations/perforations of the filter struts through the vena cava, which in turn can increase the likelihood of fractures of the arms[.]

Doc. 7319-1 at 38. This opinion is unreliable, Defendants contend, because the only basis for it is Dr. Ritchie's intuition. Doc. 7316 at 10-12. The Court does not agree.

Relying on his knowledge and experience as a materials scientist and his examination of Bard filters and review of medical records, Dr. Ritchie sufficiently

describes the basis for his opinion that fracture and other failure modes can work synergistically. He explains in his report that the effect of a fractured leg would be to "de-anchor" the filter from the IVC wall and both increase the load on remaining intact legs, making them more susceptible to fracture, and lower the filter's resistance to tilt and migration. Doc. 7319-1 at 18, 24, 28, 37. He further explains that evidence from certain G2 filters he examined shows that perforation by filter arms (and to a lesser extent the legs) can promote the fracture of limbs because perforation significantly elevates stresses on the limbs and changes the magnitude and direction of the applied loading on the filter as a whole. *Id.* at 4, 25, 29-30, 37, 47.

When asked during his deposition about his opinion that tilt can lead to perforation, Dr. Ritchie provided this explanation:

> Some degree of tilt means that you have an anchor that's not anchored, and that means that the ability of the filter to move is obviously elevated because you're not fully anchored. Once the filter starts to move, the probability of perforation is likely, and all these things relate to the possibility of fracture and . . . that's what we talked about earlier with the crack growing in different directions. So I've always seen this as what I call a vicious circle. It's a synergy of events.

Doc. 7807-1 at 21; *see* Doc. 7319-1 at 47 (explaining that the different direction of fatigue cracks in filter arms is associated with perforation).

Defendants note that Dr. Ritchie is not able to identify with certainty the probability of one failure mode causing another, or predict which failure may occur first. Doc. 7316 at 10-11. But this lack of certainty does not require exclusion of his opinions under Rule 702. The Supreme Court has explained that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." *Daubert*, 509 U.S. at 590; *see also Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) ("Lack of certainty is not, for a qualified expert, the same thing as guesswork.").

Defendants also challenge Dr. Ritchie's opinions on the ground that he impermissibly relies on Dr. McMeeking's analysis of the strains caused by perforation. Doc. 7316 at 11. But Dr. Ritchie made clear that while his opinions are confirmed by

Dr. McMeeking's calculations, he did not rely on the calculations as the basis for his opinions. Doc. 7319 at 10-11.

Dr. Ritchie's opinion that different filter failure modes can have a synergistic effect on one another is sufficiently reliable and will not be excluded.

C. Bard's Testing Was Insufficient.

Defendants contend that Dr. Ritchie is not qualified to opine about Bard's testing, but do not explain why or otherwise identify the requisite expertise that may be lacking. Doc. 7316 at 12. Dr. Ritchie is a well qualified materials scientist who has been studying fatigue and material failure for nearly 50 years. He has worked with Nitinol since the late 1970s, and has evaluated various medical implants such as heart valves and stents. His testing experience includes protocol design and using test equipment in a laboratory environment. Doc. 7319 at 4. Dr. Ritchie is qualified to opine about Bard's testing of its IVC filters.

Defendants further contend that Dr. Ritchie employed no scientific or engineering methodology, claiming that he refers to Bard's testing only as "inadequate." Doc. 7316 at 12. To the contrary, Dr. Ritchie provides the basis for his opinions both in his report and his deposition testimony. He testified that his general criticism of Bard's testing is that it "never reproduced the problem when it comes to fracture." Doc. 7319 at 28. He expanded on this view by explaining that bench testing should simulate real life results:

> So the details of the test are almost less important, but if you've got a test where everything passes and yet you put it in people's bodies and things are happening, – you know, the actual implant in the body is the better test, and so your lab test is obviously not reflecting reality.

Id.; *see also* Doc. 7807-1 at 23 ("I've been critical of a lot of the tests that Bard did, because they never had a failure.").

In his report, Dr. Ritchie discusses two corrosion and fatigue tests Bard conducted on the Recovery filter. He finds the first one to be inadequate because "[t]oo few filters were tested, the test was too short (respiratory cycles are typically 15/min meaning that

[the] test simulated ~4 rather than 10 years), [and] it was conducted on one size filter (which may not have been the most highly stressed filter)." Doc. 7319 at 33. He opines that the most critical deficiency is that the test "did not simulate all modes of loading that the filter experiences *in vivo*" and was "never truly validated as no filters ever failed[.]" *Id.* He finds the second test to be deficient for similar reasons, explaining that the stress employed was "below the fatigue limit for [the] Nitinol wire, implying these test specimens would never fail, regardless of the number of loading cycles applied." *Id.* at 34. He further opines that no similar independent testing appears to have been performed for the G2 filter, and that Bard instead "relied on the same inadequate fatigue and corrosion testing performed on the Recovery." *Id.*

Bard disagrees with Dr. Ritchie's opinion that its testing was flawed because it failed to replicate filter failures (Doc. 8230 at 7), but this disagreement does not render his opinions unreliable for purposes of Rule 702. Bard will be free to cross examine Dr. Ritchie at trial. The Court will not exclude his opinions about Bard's testing.

D. The SNF is a Safer Alternative Filter.

Dr. Ritchie testified that the SNF is a safer filter than the Recovery and G2. Doc. 7319 at 42-44. The Court agrees with Defendants that Dr. Ritchie employed no reliable methodology in forming this opinion. Doc. 7316 at 13. As Plaintiffs concede, "his opinion regarding SNF is based on the statistical analysis performed by Dr. Betensky of SNF's adverse events relative to other Bard filters as well as studies in the published literature regarding comparative filter complication rates." Doc. 7807 at 9. But as explained above, Dr. Ritchie made no effort to verify Dr. Betensky's work, and mentions her analysis in his report only by way of background. Doc. 7319 at 41. Dr. Ritchie cannot simply repeat Dr. Betensky's opinions as his own.

Moreover, unlike Dr. McMeeking, Dr. Ritchie has performed no assessment of the SNF's design, manufacture, or structural integrity. *See* Doc. 7318-4 at 9-17. And he mentions the SNF only briefly in his report. Doc. 7319-1 at 15 (noting that the filter's original design drawings called for a 45º chamfer).

Plaintiffs have failed to establish a reliable foundation for Dr. Ritchie's opinion that the SNF is a safer, alternative filter. The opinion will be excluded.[2]

IT IS ORDERED that Defendants' motion to exclude the opinions of Robert Ritchie, Ph.D. (Doc. 7316) is **granted in part** as set forth in this order.

Dated this 8th day of February, 2018.

David G. Campbell
United States District Judge

[2] Defendants also assert that the opinions of Dr. Ritchie challenged in their motion will not assist the jury, but provide no explanation for this argument. Doc. 7316 at 3.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Drs. David Garcia and Michael Streiff (collectively, the "Doctors"). Doc. 7294. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. Blood clots develop in the IVC from a condition called venous thromboembolism or "VTE." IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs.

People at risk for VTE may be prescribed blood-thinning medications to help prevent blood clotting, but these medications do not prevent clotting for certain people at high risk for VTE and may not be an option for certain patients who could experience

thromboembolic events during surgery. In those situations, physicians may recommend implanting an IVC filter to catch any blood clots before they reach a vital organ.

IVC filters such as Bard's Simon Nitinol Filter ("SNF") originally were designed to be implanted permanently. Because some patients need only temporary filters, medical device manufacturers such as Bard developed retrievable filters. This MDL involves seven different versions of Bard retrievable filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injuries. Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn physicians and patients about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

The Doctors are board-certified hematologists whom Plaintiffs have identified as expert witnesses. Dr. Garcia currently serves as the medical director of anti-thrombotic therapy and professor of hematology at the University of Washington. Dr. Streiff serves as the medical director of anticoagulation services and a professor of hematology at John Hopkins University. The Doctors have authored a joint expert report on physician expectations and the risks and benefits of IVC filters in the prevention and treatment of VTE. Doc. 7294-2 at 2-8.[1] They have also prepared a two-page addendum based on a review of Dr. Kessler's report. *Id.* at 9-10. Dr. Garcia has also offered opinions in the bellwether case brought by Plaintiff Doris Jones. Doc. 7299.

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[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

Defendants do not dispute that the Doctors have expertise in the field of clinical hematology, nor do they seek to exclude their risk-benefit opinions. Rather, Defendants ask the Court to exclude three categories of opinions: (1) opinions based on Dr. Kessler's report, (2) physician expectations and Bard's corporate conduct, and (3) Dr. Garcia's opinions in the Jones case. Doc. 7302 at 2. The Court will address each category.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Opinions Based on Dr. Kessler's Report.

The opinions set forth in the addendum should be excluded, Defendants argue, because the Doctors merely act as conduits for Dr. Kessler's opinions without having evaluated or verified his work. Doc. 7294 at 2-4. The Court agrees.

In their report, the Doctors rely on their own clinical experiences treating patients with VTE and their research into the proper use of IVC filters to opine about physician expectations and the risks and benefits of IVC filters. Doc. 7294-2 at 5-8. Their addendum, by contrast, contains opinions unrelated to these subjects and for which the Doctors provide no methodology or foundation other than a review of Dr. Kessler's

report. *Id.* at 9-10. The Doctors opine about Bard's knowledge and intent, the company's internal testing procedures, and statistical studies purportedly showing increased risks with the Recovery and G2 filters. Specifically, the Doctors opine that:

- "Bard misled the FDA on the tendency of the Recovery filter to migrate when challenged by increased venous pressure" (*id.* at 9, ¶ 1);
- "Bard should not have marketed the [Recovery] filter since its performance was significantly poorer than the comparator, was not performing as intended, expected and represented prior to marketing and failed safety thresholds for migration" (*id.* ¶ 3);
- The Recovery "was associated with statistically significant more complications and . . . migration-related deaths" than the SNF, and "Bard knew this from an internal statistical analysis" (*id.* ¶ 4);
- "Bard knew of these deficiencies . . . but continued to market the device" (*id.* at 10, ¶ 5);
- "Bard knew that the [Recovery], G2 family and the Eclipse filters did not fulfill their own internal performance standards and would pose an increased risk . . . to patients" (*id.* ¶ 7).

Plaintiffs admit that the Doctors relied on Dr. Kessler's report for these opinions, asserting that it is not uncommon for experts to base their opinions in part on the testimony of another expert with more specialized knowledge. Doc. 7808 at 7. But the Doctors cannot merely act as conduits for Dr. Kessler's opinions about Bard's communications with the FDA and increased filter risks. *See* Doc. 9771 at 5; *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013). The addendum and deposition testimony suggest they are doing just that. They state that they read Dr. Kessler's report and formed their opinions "based upon *his* review of documents" and "[t]he data provided in *his* summary[.]" Doc. 7294-2 at 9 (emphasis added). Their opinion that Bard knew of filter defects is based on internal documents "quoted in Dr. Kessler's report[.]" *Id.* at 10, ¶ 5. And the Doctors' ultimate conclusion that Bard knew its filters did not

meet performance standards but continued to market the devices is based solely on "the cumulative data in Dr. Kessler's report." *Id.* ¶ 7.

Dr. Streiff testified that he made no effort to verify Dr. Kessler's work and instead simply took the data and findings from his report and put them in the addendum without change. Doc. 7294-3 at 15-20. Dr. Garcia testified that, other than reading the Asch study and Dr. Betensky's analysis referenced in Dr. Kessler's report, he did nothing to assess the reliability of the underlying data and documents used by Dr. Kessler. Doc. 7299-1 at 27-29. Dr. Garcia could not describe the methodology Dr. Kessler employed, and admitted that he essentially is "repeating what Kessler found[.]" *Id.* at 26. As the Court previously has held, an expert cannot simply repeat the opinions of other experts as his own when he has done nothing to verify the accuracy of the opinions. Doc. 9772 at 5; *see In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016).

Moreover, the Doctors have no expertise in the FDA regulatory process, corporate compliance or ethics, or the design, testing, and marketing of IVC filters. Docs. 7294-3 at 4-7, 7299-1 at 9-11. They identify no training, experience, or specialized knowledge that would enable them to opine about Bard's internal knowledge, or what Bard did or failed to do in the development of its IVC filters. Such opinions are outside the realm of their expertise and are not supported by sufficient facts and data or evaluated through reliable principles and methods. Fed. R. Evid. 702(b), (c).

The Court will exclude the opinions set forth in the Doctors' addendum. *See* Doc. 7294-2 at 9-10.

B. Physician Expectations and Corporate Conduct.

Defendants contend that the Doctors are not qualified to offer the following opinions set forth in the "Physician Expectations" section of their report: (1) "in order for physicians to make reasonable risk-benefit assessments regarding filters, it is critically important that manufacturers of IVC filters continuously apprise the clinicians who order and implant IVC filters about their safety profile, performance characteristics, design

problems, and internal risk assessments," and (2) "Bard's complete transparency about the safety profile of its IVC filters is paramount." Doc. 7294 at 5 (quoting Doc. 7294-2 at 7-8). Plaintiffs argue that the Doctors are qualified to give these opinions based on their expertise in the field of hematology and their clinical training and experience treating patients with VTE. Doc. 7808 at 4-6. The Court agrees.

Dr. Streiff's clinical practice and research focuses on the management of VTE, including the appropriate use of IVC filters. Doc. 7294-2 at 4. He regularly makes therapeutic decisions for patients with VTE, and must decide whether to manage the condition with blood-thinning medications or an IVC filter. *Id.*

Dr. Garcia has been treating patients with VTE for nearly 15 years, including patients who have suffered IVC filter failures. *Id.* at 3. He has reviewed more than 50 papers relevant to the safety and efficacy of IVC filters, and often is part of the decision-making process in which the risks and benefits of an IVC filter are weighed. *Id.*; Doc. 7808-1 at 8-13. Although he rarely recommends an IVC filter given his doubts about the benefits of implanting one, he recommended a filter last year for a patient who had suffered a traumatic brain injury and could not continue on blood-thinning medications. Doc 7808-1 at 7. He explained that this decision was made only after a long discussion with the patient about the risks and benefits of an IVC filter. *Id.* at 8.

The Court finds that the Doctors have sufficient knowledge and experience to opine about the information hematologists reasonably expect to receive from IVC filter manufacturers. *See Primiano v. Cook*, 598 F.3d 558, 566 (9th Cir. 2010) (noting that "a doctor's experience might be good reason to admit his testimony"). Defendants note that the Doctors have no expertise in implanting or removing IVC filters. Doc. 7294 at 5. But the Doctors make recommendations that patients have IVC filters implanted. Doc. 7294-2 at 3-4. And Dr. Garcia has testified that while the implanting physician must obtain informed consent for the procedure, the treating hematologist has a duty to inform the patient about the long-term risks and benefits of IVC filters. Doc. 7808-1

at 11-12. Defendants will be free to bring out on cross examination that the Doctors do not implant or remove IVC filters, but this is no basis for excluding their opinions.

Defendants contend that the opinions are nothing more than personal beliefs based solely on a review of Dr. Kessler's report. Doc. 7294 at 5. The Court does not agree. Defendants cite many pages of Dr. Garcia's deposition transcript, but identify no specific testimony showing reliance on Dr. Kessler's report for these opinions. *Id.* (citing Doc. 7299-1 at 13-20). Dr. Garcia did note that he had some concern as to whether Bard has been completely transparent in light of Dr. Kessler's report (Doc. 7299-1 at 20), but this concern is not the sole basis for his opinion that it is important for IVC filter manufacturers to disclose safety information to physicians. When asked about the basis for that opinion, Dr. Garcia explained:

> I think this is a statement that could apply to the manufacture of any device or medication that's going to be prescribed or deployed by a treating physician. . . . I think we wanted to emphasize it here because when you have an intervention – the benefit or efficacy of which is highly questionable or poorly established – ensuring that the doctors who are choosing to use it know as much detail as possible about its risks, has heightened importance.

Id. at 14.

Dr. Garcia provided a similar response when asked about the opinion that Bard's transparency regarding safety concerns is paramount:

> When you have an intervention for which the efficacy is poorly established or not established, the importance of notifying physicians about any possible risk or safety concern associated with that intervention becomes even higher than treatments, where we at least know . . . there is some well-documented benefit.

Id. at 19. Dr. Streiff testified that he and Dr. Garcia decided to offer their opinions about the importance of receiving information from IVC filter manufacturers after reviewing Dr. Kessler's report. Doc. 7294-3 at 12. But given the Doctors' vast experience treating patients with VTE, it is not clear that the report is the sole basis for their opinions.

The Court cannot conclude from the cited testimony that the opinions about physician expectations are mere personal beliefs based solely on Dr. Kessler's report. Defendants may object at trial if they believe the Doctors are simply parroting Dr. Kessler's findings, or offering an impermissible corporate conduct opinion under the guise of physician expectations. *See* Doc. 8229 at 7.

Defendants further contend that the Doctors' opinions about physician expectations are irrelevant to Plaintiffs' failure to warn claims because the relevant inquiry is whether their treating physicians were adequately warned under their respective jurisdictions. Doc. 7294 at 6. But Defendants make no effort to show that this is the relevant inquiry under the law governing the bellwether trials, or that the reasonable expectations of non-treating physicians have no probative value. The final decision on this issue must await trial.

The Court notes that some of the Doctors' opinions are couched in terms of Bard's "obligation" rather than physician expectations. Doc. 7294-2 at 7. As explained above, the Doctors are not regulatory or corporate experts, and they will not be permitted to opine on Bard's obligations. Their opinions will be limited to physician expectations.[2]

C. Dr. Garcia's Opinions in the Jones Case.

Plaintiff Jones has a fragment of an Eclipse filter lodged in her right pulmonary artery. Based in part on a review of her medical records, Dr. Garcia offers several opinions about the potential consequences of the fragment remaining in the artery. Doc. 7299. Defendants ask the Court to exclude as unreliable all of Dr. Garcia's opinions, but address only two in their motion: (1) "the presence of a foreign body in a pulmonary artery branch represents a permanent, significant risk factor for the development of in situ thrombosis," and (2) Plaintiff "should be therapeutically

[2]Defendants argue in their reply that the Doctors' opinion that "questions remain as to whether [IVC filters] are effective" is irrelevant because the opinion says nothing about physician expectations regarding Bard filters. Doc. 8229 at 6, 8-9 (quoting Doc. 7294-2 at 7). The Court will not grant relief on an argument not made in Defendants' motion. Defendants may object if this opinion is offered and Defendants believe it to be irrelevant.

anticoagulated indefinitely." Doc. 7294 at 6-7. Defendants say nothing about Dr. Garcia's opinions that the filter fragment "can result in turbulent blood flow, which promotes local coagulation"; that "the mere presence of the filter in a pulmonary artery branch can result in a hyper-coagulable condition which promotes the creation of a local thrombus"; or that "it is likely that the filter fragment has caused injury to the inner wall of the pulmonary artery." *Id.* at 6. The Court will not exclude these opinions.

Regarding the first challenged opinion, Defendants contend that it should be excluded because Dr. Garcia reviewed no imaging of the fragment and has identified no medical literature to support his extrapolation from entire IVC filters causing thrombosis to filter fragments in other parts of the body causing thrombosis. Doc. 7294 at 7. Plaintiffs counter that the opinion is sufficiently reliable under Rule 702 and *Daubert* because it is based on Dr. Garcia's experience and training as a hematologist, the methodology he routinely employs in his clinical practice, and the generally accepted view that foreign objects in the body can promote thrombosis. Doc. 7808 at 9-12. The Court agrees.

Dr. Garcia explains in his report that "the body has a biochemical response to a foreign object exposed to circulating blood," and this response "promotes the formation of thrombosis on the foreign body (in this case, the filter fragment)." Doc. 7299 at 2. He further explained this phenomenon during his deposition:

> [A] variety of foreign objects again – and I've cited clinical examples . . . of those – when they're exposed to circulating blood, they activate factor XII, which is one of the clotting proteins that are involved in the so-called contact activation or intrinsic activation pathway. And that triggers . . . a series of chain reactions that ultimately can lead to the formation of a blood clot. And it's entirely stimulated by contact with foreign surfaces. And I have no reason to think that a filter fragment would be an exception to a rule that's certainly followed by many other foreign bodies.

Doc. 7808-1 at 31; *see id.* at 26, 29 (noting that studies show that IVC filters and other medical implants, such as catheters and heart valves, promote thrombosis).

The Court finds that Dr. Garcia has provided a sufficiently reliable basis for his

opinion that a foreign body in the pulmonary artery presents a significant risk for thrombosis. The fact that Dr. Garcia identifies no medical literature showing that IVC filter fragments can promote thrombosis does not render his opinion inadmissible. "The *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable to [testimony] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *See United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000).

Defendants note that Dr. Garcia is not able to quantify the increased risk or state with certainty that the filter fragment will cause thrombosis. Doc. 7316 at 10-11. But this lack of certainty does not require exclusion of his opinion under Rule 702. The Supreme Court has explained that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." *Daubert*, 509 U.S. at 590; *see also Primiano*, 598 F.3d at 565 ("Lack of certainty is not, for a qualified expert, the same thing as guesswork.").[3]

Regarding the other challenged opinion – that Plaintiff should receive anticoagulation therapy indefinitely – the Court agrees with Defendants that Dr. Garcia does not know enough about Plaintiff's current health condition to give this opinion. Doc. 7294 at 6-7. The opinion is based solely on Dr. Garcia's view that Plaintiff is at risk for thrombosis due to the filter fragment. Doc. 7299 at 3. But Dr. Garcia conceded during his deposition that he cannot say whether Plaintiff is a candidate for anticoagulation therapy because he does not have enough details about her health to fully assess the risks of such therapy. Doc. 7299-1 at 33, 44. And he acknowledged that he does not even know whether Plaintiff has ever been prescribed anticoagulation therapy, either before or after the filter fragment was discovered. *Id.* at 44. In short, Dr. Garcia has no reliable basis for opining that Plaintiff should receive anticoagulation therapy indefinitely. This opinion will be excluded.

[3] Defendants further note that it is unclear which medical records Dr. Garcia reviewed. Doc. 7294 at 6. Dr. Garcia made clear during his deposition that he reviewed Plaintiff's treatment records. Doc. 7299-1 at 31.

IT IS ORDERED that Defendants' motion to exclude the opinions of Drs. David Garcia and Michael Streiff (Doc. 7294) is **granted in part and denied in part** as set forth in this order.

Dated this 12th day of February, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Plaintiffs have filed a motion to exclude the opinions of Drs. Clement Grassi and Christopher Morris (collectively, the "Doctors"). Doc. 7324. The motion is fully briefed, and the parties agree that oral argument is not needed. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs, among other things, allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs

assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that Bard filters are safe and effective and that the medical community is aware of the risks associated with IVC filters.

The Doctors are interventional radiologists whom Defendants have identified as expert witnesses on various issues related to Bard filters. Plaintiffs do not dispute that the Doctors have expertise in the field of interventional radiology. Rather, Plaintiffs seek to exclude certain opinions purportedly based on (1) the criminal law standard of certainty, and (2) speculation and anecdotal personal experience. Doc. 7324.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Opinions Based on a High Level of Certainty.

Plaintiffs seek to exclude Dr. Morris's testimony that he "reached a high level of certainty in his opinions" which means "more than 90 percent." Doc. 7324 at 3-4 (citing Doc. 7324-2 at 18-21). Plaintiffs similarly object to Dr. Grassi's testimony that in forming his opinions he looks for evidence that makes him feel "certain beyond any reasonable doubt." *Id.* at 5 (citing Doc. 7324-2 at 44). This testimony should be

excluded, Plaintiffs contend, because *Daubert* does not require scientific testimony to be known to a certainty. *Id.* at 7-8; Doc. 8209 at 3. But *Daubert* addressed the threshold reliability requirements for admissibility under Rule 702, noting that although certainty is not required, expert testimony must be based on "more than subjective belief or unsupported speculation." 509 U.S. at 590. *Daubert* says nothing about the exclusion of testimony where the expert is certain of his opinions.

Defendants note, correctly, that the essence of Plaintiffs' objection seems to be that the Doctors are *too* certain of their opinions. Doc. 7797 at 2. Plaintiffs explain in their reply that the problem is not that the Doctors hold their opinions to a high degree of certainty, but that they "applied the heightened standard *in forming their opinions*." Doc. 8209 at 3 (emphasis in original). Plaintiffs assert that the Doctors' testimony will confuse and mislead the jury and prejudice Plaintiffs by requiring them to prove their case to a higher level of certainty than the law requires. *Id.* But the Court, not the Doctors or any other witnesses, will instruct the jury on the law, and the instructions given will include the appropriate burdens of proof in a civil case. *See* Doc. 9433 at 15.

The Court will not exclude testimony regarding the Doctors' certainty of their opinions. If Plaintiffs believe the Doctors are attempting to instruct the jury on legal standards, they may object. If Plaintiffs believe a clarifying jury instruction is needed, they may propose one.

B. Opinions Based on "Speculation" and Anecdotal Personal Experience.

Plaintiffs contend that Dr. Morris admitted that his opinion regarding asymptomatic limb fractures is mere "speculation." Doc. 7324 at 11 (citing Doc. 7324-2 at 24-25). Defendants respond that Plaintiffs take Dr. Morris's testimony out of context, and that he found Plaintiffs' hypothetical to be speculative, not his own opinion. Doc. 7797 at 13-15. Plaintiffs do not address this issue in their reply.

The Court cannot conclude from the deposition testimony that Dr. Morris conceded that his opinion was mere speculation. Plaintiffs may cross examine him on this point at trial.

Plaintiffs object to Dr. Grassi's statement that "[in his] own experience, [he has] not encountered unexpectedly high complication rates with Bard filter devices." Doc. 7324 at 12; *see* Doc. 7798-1 at 2. Plaintiffs note that the statement is anecdotal and based on Dr. Grassi's personal experience, but do not explain why this renders the statement inadmissible. Dr. Grassi may rely on his own clinical experience in stating his opinions, just as Plaintiffs' experts are allowed to do. *See McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092 (D. Or. 2010); *Primiano v. Cook*, 598 F.3d 558, 566 (9th Cir. 2010). Testimony about a doctor's own clinical experiences is not based on mere speculation. Plaintiffs may cross examine Dr. Grassi about the basis for his statement and the number of patients with Bard filters he has encountered, but Plaintiffs have identified no basis for excluding the statement under Rule 702.

IT IS ORDERED that Plaintiffs' motion to exclude defense expert opinions based on their use of the criminal law standard of certainty (Doc. 7324) is **denied**.

Dated this 21st day of February, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Plaintiffs have filed a motion to exclude the opinions of Dr. Christopher Morris. Doc. 7320. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege

that Bard failed to warn physicians and patients about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that Bard filters are safe and effective and that the medical community is aware of the risks associated with IVC filters.

Defendants have identified Dr. Morris, an interventional radiologist, as an expert witness on various issues related to Bard filters. Dr. Morris graduated from Case Western Reserve University School of Medicine in 1985. He completed his residency in diagnostic radiology at Ohio State University, and his fellowship in vascular and interventional radiology at Massachusetts General Hospital. He currently serves as a professor of radiology and surgery at the University of Vermont, and is a member of the American College of Radiology and the Society of Interventional Radiology. Doc. 7800-1 at 2-3.[1]

Plaintiffs do not dispute that Dr. Morris has expertise in the field of interventional radiology and the use of IVC filters. Rather, Plaintiffs ask the Court to exclude his opinions that (1) Bard filters are safe and effective, and (2) medical imaging should not be part of a patient's routine follow-up care and has no bearing on the decision to remove a filter. Doc. 10070 at 7-18. The Court will address each opinion.[2]

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods

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[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

[2] Plaintiffs also challenge Dr. Morris's opinion in a related class action that the risks of late-stage retrieval outweigh the risk of leaving the filter in place. *Id.* at 18-19 (citing Doc. 7322 at 13). This issue is moot because the class action has been dismissed. *See* Docs. 105-08, *Barraza v. C. R. Bard, Inc.*, No. CV-16-01374-PHX-DGC.

to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Opinion on Safety and Effectiveness.

In rebutting the report of one of Plaintiffs' experts, Dr. Morris opines that Bard filters are safe and effective. Doc. 7800-1 at 22. Dr. Morris states that this opinion is based on his "review of the available literature and [his] personal experience." *Id.*

Plaintiffs contend that the opinion is unreliable because Dr. Morris discounted studies showing high complication rates and did not consider Bard's internal data showing that the filters were subject to failure. Doc. 10070 at 8-13. Defendants counter that the opinion is sufficiently reliable because Dr. Morris relies on both his personal experience with IVC filters and his interpretation of the relevant literature, and that Plaintiffs' mere disagreement with the opinion is no basis for exclusion under Rule 702. Doc. 7800 at 2-13. The Court agrees with Defendants.

Plaintiffs do not dispute that a doctor's experience can serve as a sufficient foundation for opinions about the medical devices the doctor uses in his clinical practice. Doc. 7812 at 14 (citing *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)). Dr. Morris has been treating patients with IVC filters for more than 25 years. Doc. 7800-1 at 2. His team has implanted and removed hundreds of such filters, including more than 200 Bard filters. *Id.* at 3; Doc. 7800-2 at 4-5. This clinical experience is sufficient to satisfy the threshold reliability requirements of Rule 702. *See Primiano*, 598 F.3d at 567 ("Dr. Weiss's background and experience, and his explanation of his opinion, leave

room for only one conclusion regarding its admissibility. It had to be admitted."); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 420-21 (S.D.N.Y. 2016) (the expert's "experience as a medical doctor specializing in OB/GYN and his familiarity and experience in placing and teaching how to place IUDs . . . are indicative of the reliability of his opinions").

Moreover, Dr. Morris considered the relevant medical literature, including studies showing that Bard filters have high complication rates. Doc. 7800-1 at 22-28. Plaintiffs argue that Dr. Morris improperly disregarded several specific studies (Doc. 10070 at 8-9), but Dr. Morris's report specifically addresses those studies and explains why he views them as flawed (Doc. 7800-1 at 25-26). Plaintiffs may find his reasoning unpersuasive (Doc. 8210 at 5-7), but that is no basis for excluding his opinions. Plaintiffs can cross examine Dr. Morris about his evaluation of the studies at trial. *See In re Mirena*, 169 F. Supp. 3d at 419 (finding that the expert's rejection of the leading study on which the plaintiffs relied was a basis for cross examination but not exclusion).

Plaintiffs argue that Dr. Morris's opinions are unreliable because he did not review internal Bard documents on which Plaintiffs' experts relied. But Dr. Morris explained that interventional radiologists never rely on internal corporate documents for their clinical decisions, and that he considers such documents to be a less reliable source of information than his clinical practice or the peer-reviewed studies he cites. Doc. 7800 at 10. Again, Plaintiffs can assert in argument and cross examination that Dr. Morris did not consider internal Bard data. These criticisms are fair game for trial, but they do not render his opinions inadmissible under Rule 702. *See In re Mirena*, 169 F. Supp. 3d at 427 ("To whatever extent Defendants' public or internal statements conflict with its experts' opinions[,] . . . that will be a problem for Defendants that Plaintiffs may exploit via cross-examination and argument. But Defendants' experts' failure to confront alleged conflicting statements made by Bayer does not warrant exclusion under *Daubert*.").

Plaintiffs' reliance on *In re Bextra & Celebrex Marketing Sales Practices and Product Liability Litigation*, 524 F. Supp. 2d 1166 (N.D. Cal. 2007), is misplaced. The

expert in that case sought to provide a causation opinion based on two observational studies which were contrary to epidemiological studies that included 97% of the adverse event reports. *Id.* at 1176. The court found that the expert was not qualified to give the opinion in part because he had no experience with the medical risks at issue, had no epidemiological training or experience, and had never participated in an observational study. *Id.* The expert's lack of relevant experience and training, among other problems, led the court to conclude that his causation opinion was not "good science." *Id.* at 1176-78. The same cannot be said of Dr. Morris's opinions.

The other cases Plaintiffs cite are inapposite. *See In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1250-51 (W.D. Wash. 2003) (excluding "scattershot" causation opinion where the expert failed to cite evidence in support of the 35 different biological mechanisms he claimed could have caused the plaintiffs' injuries); *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1067-68 (C.D. Cal. 2013) (excluding opinion that the NHTSA was biased toward finding mechanical and driver error where the expert failed to describe his role in investigations or otherwise explain how his experience as an attorney for the agency provided a sufficient basis for his opinion); *In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.*, 984 F. Supp. 2d 1021, 1040 (C.D. Cal. 2013) (excluding opinion where 90% of the loans included in the sample size were at issue in the litigation and the methodology failed to account for selection bias and systematic error); *Wise v. C. R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *15 (S.D. W. Va. Feb. 7, 2015) (finding a design expert's reliance on internal documents not to be problematic where he used them to reinforce his opinion rather than to narrate corporate conduct); *Trevino v. Bos. Sci. Corp.*, No. 2:13-cv-0167, 2016 WL 2939521, at *12-13 (S.D. W. Va. May 19, 2016) (excluding design-related opinions where the expert did not review the defendant's design protocols).

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B. Opinions on Medical Imaging.

Dr. Morris offers opinions rebutting Plaintiffs' claim that medical imaging is a necessary follow-up procedure for all patients who have Bard filters. Doc. 7800-1 at 13-17. Plaintiffs challenge as unfounded the following statements in Dr. Morris's report:

- "To my knowledge, no appropriate medical society or consensus group has recommended medical imaging as a specific component of the recommended follow-up protocol." Doc. 7800-1 at 15.
- "It is notable that no authoritative society or organization has specifically recommended imaging as part of a surveillance or medical monitoring program regarding [IVC filters]." *Id.* at 17.
- "Medical imaging of the [IVC filter], other than determining whether or not the [IVC] and indwelling [filter] are patent and free of thrombus, has no bearing on whether or not the [filter] should be removed." *Id.* at 13.
- "[I]n an asymptomatic patient with an [IVC filter], the status of the filter has no bearing on whether or not it should be removed . . . . Therefore, imaging does not contribute to the clinical decision on whether or not to remove a [filter]." *Id.* at 16.

Doc. 10070 at 13-18. Plaintiffs accuse Dr. Morris of failing to recognize that a guideline published by the Society of Interventional Radiologists ("SIR") recommends "[i]maging of [the] vena cava prior to retrieval." *Id.* at 14 (citing Doc. 7321-1 at 83). Plaintiffs also cite certain medical studies that recommend close monitoring of implanted IVC filters, noting that one of the studies suggests the use of imaging for patients with Recovery filters. *Id.* at 15.

Defendants counter that Plaintiffs mischaracterize Dr. Morris's opinions and the medical literature. Doc. 7800 at 13-20. According to Defendants, Dr. Morris believes that patients with IVC filters should receive clinical follow-up care but that asymptomatic patients do not require routine imaging. *Id.* at 14-15. Defendants also note that the SIR guidelines set forth reporting standards for medical literature purposes,

not recommendations for clinicians to follow in treating patients with IVC filters. *Id.* at 15-18.

Having read the quoted statements in the context of Dr. Morris's full report, the Court finds no basis for excluding them under Rule 702. The parties and their experts vigorously disagree on whether the medical literature suggests that imaging should be part of routine follow-up care. Plaintiffs may cross examine Dr. Morris on this point and elicit relevant testimony from their own experts, but they have not shown that Dr. Morris's interpretation of the medical literature is so unreliable that it should be excluded under Rule 702.

Similarly, Plaintiffs may disagree with the opinion that imaging has no bearing on the decision to remove a filter from an asymptomatic patient, but they have not shown that the opinion is based on Dr. Morris's mere "*ipse dixit*." Doc. 10070 at 18. Dr. Morris explained that the decision to remove a filter is a clinical one that "makes a specific determination of whether or not there is ongoing indication for [IVC] filtration." Doc. 7800-1 at 14. And he provided the reasons that, in his opinion, this determination is independent of the status of the filter. *Id.* Given this explanation and Dr. Morris's experience removing IVC filters, the Court cannot conclude that his opinion is so unreliable that it should be excluded under Rule 702.

IT IS ORDERED that Defendants' motion to exclude the opinions of Dr. Christopher Morris (Doc. 7320) is **denied**.

Dated this 21st day of February, 2018.

David G. Campbell
United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL15-2641-PHX DGC
Debra and James Tinlin, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV16-0263-PHX-DGC **ORDER**

Defendants move to strike and exclude the opinions of Plaintiffs' engineering expert, Dr. Robert McMeeking. Docs. 14016, 15075. The motions are fully briefed. Docs. 14655, 14840, 15752, 16012. Defendants request oral argument, but it will not aid the Court's decision. *See* Fed. R. Civ. P. 78(b); LRCiv 7.2(f). For reasons stated below, the Court will deny the motion to strike and deny in part and grant in part the motion to exclude.

I. Motion to Strike General Opinions in the Tinlin Report.

Plaintiffs disclosed Dr. McMeeking's initial report on the design of Bard IVC filters on March 3, 2017, the deadline for expert disclosures on common issues in this MDL. Doc. 14018-1; *see* Doc. 3685 at 3. The report includes Dr. McMeeking's general opinions

about the Recovery filter, the device at issue in the Tinlin case. Doc. 14018-1 at 27-82. Plaintiffs disclosed Dr. McMeeking's report for the Tinlin case on December 17, 2018. Doc. 14018.

Defendants do not challenge the case-specific opinions in the Tinlin report as untimely. Rather, Defendants contend that Dr. McMeeking should not be permitted to reiterate or summarize his general opinions about the Recovery's design in the Tinlin report because this will allow Plaintiffs to get "a second bite at the apple by re-writing and revising" Dr. McMeeking's original report. Doc. 14016 at 4. But Defendants identify no rewritten or revised opinion in the Tinlin report. Instead, Defendants highlight the case-specific opinions and claim that anything not highlighted is a "generic opinion that Dr. McMeeking has either copied from his original report or added to his opinions in the original report." Doc. 14840 at 2; *see* Doc. 14018 (highlighted report).

The Court cannot conclude that Dr. McMeeking (or any other expert in this MDL) should be precluded from restating general opinions in case-specific reports to provide necessary context and a basis for case-specific opinions. *See Coleman v. Home Depot U.S.A., Inc.*, No. 1:15-CV-21555-UU, 2016 WL 4543120, at *1 (S.D. Fla. Mar. 21, 2016) (denying motion to strike in part where the expert merely reiterated opinions set forth in his initial report); *U.S. Fire Ins. v. Omnova Sols., Inc.*, No. 10-1085, 2012 WL 5288783, at *3 (W.D. Pa. Oct. 23, 2012) (denying motion to exclude supplemental report that did not expand or alter opinions in the original report). For example, Dr. McMeeking may restate his general opinion that the "Recovery filter has significant problems relating to migration (including caudal migration), tilt, perforation, and fracture" in concluding that "Ms. Tinlin's filter failed in all of those ways." Doc. 14018 at 3. Defendants' proposed eliminations from the Tinlin report (the portions not highlighted) would result in a host of conclusory case-specific opinions unconnected to Dr. McMeeking's general opinions about the Recovery's design. A primary purpose of a case-specific report is for the expert

to apply his general opinions to the facts of the case. This necessarily requires the expert to reiterate or summarize some of his general opinions.[1]

The Court agrees with Defendants that Dr. McMeeking may not offer new or materially revised opinions about the Recovery's design in the Tinlin report, but Defendants provide no basis for the Court to distinguish between any new or revised opinion and those that are merely being restated. The Court accordingly will deny the motion to strike portions of the Tinlin report. *See Curlee v. United Parcel Serv., Inc.*, No. 3:13-CV-00344-P, 2014 WL 11516719, at *8 (N.D. Tex. Dec. 12, 2014) (finding it unnecessary to strike an expert's supplemental report where it "[did] not provide new expert opinions, only reiterate[d] his past opinions"); *Adams v. United States*, No. 03-0049-E-BLW, 2009 WL 982031, at *1 (D. Idaho Apr. 9, 2009) (finding that it would serve little purpose to exclude portions of a rebuttal report that reiterated the expert's initial opinions where the report would not be admitted into evidence); *Vista Ridge Dev., LLC v. Assurance Co. of Am.*, No. 08-cv-01205-ZLW-KLM, 2009 WL 960718, at *1 (D. Colo. Apr. 7, 2009) (denying motion to strike expert affidavit where the defendant failed to direct the court to any opinion in the affidavit that went beyond the information contained in the original report).[2]

II. Motion to Exclude Case-Specific Opinions in the Tinlin Report.

Defendants move to exclude Dr. McMeeking's opinions regarding alternative designs for the Recovery and Bard's "choices" in designing the filter. Docs. 15075 at 2-3, 16012 at 9-11.

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[1] Defendants' proposed eliminations also include Dr. McMeeking's qualifications, hourly rate, and the materials he relied on in forming his opinions. *See id.* at 2, 7. This information clearly is permissible.

[2] Plaintiffs avow that Dr. McMeeking's opinions about the Recovery's design in the Tinlin report do not differ materially from his prior opinions. Doc. 14655 at 3. Plaintiffs also assert, however, that any "minor modifications" are justified because "the bellwether process should allow clarification or refinement of opinions as the parties continue the process." *Id.* at 1-2. The bellwether process provides no basis for a party to disclose modified expert opinions after the deadlines for expert disclosures set forth in the Court's case management orders. *See* Docs. 519 (CMO No. 8), 3685 (CMO No. 18).

A. Alternative Designs.

In the Tinlin report, Dr. McMeeking discusses the Recovery's failure modes and proposes several design features that he believes would have helped reduce the failures. Doc. 15078-1 at 3-4. Specifically, he opines that:

- Alternative design features available to Bard before Ms. Tinlin received her Recovery filter include "caudal anchors, penetration limiters, two-tier design, and a better (smoother and rounded) chamfer at the mouth of the 'cap' on the filter";
- "Many of these design features existed in other IVC filter products already on the market, including the Simon Nitinol Filter, the Cook Gunther Tulip filter, the Greenfield filter, and the Cook Bird's Nest filter"; and
- "[I]ncorporation of these features would have helped to mitigate or eliminate the failures [he] identified and that occurred in [Ms.] Tinlin's filter."

Id. at 4.

Defendants seek to preclude these opinions because Dr. McMeeking testified in his deposition that he cannot say whether the design changes would have prevented Ms. Tinlin's injuries, and does not know by what percentage the risk would have been reduced. Docs. 15075 at 4. These admissions, Defendants contend, show that Dr. McMeeking's opinions are unreliable and do not fit Ms. Tinlin's case as required by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). *Id.* at 2; Doc. 16012 at 2-4, 9-10. The Court does not agree.

Wisconsin's product liability statute, Wis. Stat. § 895.047, requires Plaintiffs to show that that a reasonable alternative design would have "reduced" the Recovery's risk of harm. § 895.047(1)(a); *see Janusz v. Symmetry Med. Inc.*, 256 F. Supp. 3d 995, 1000 (E.D. Wis. 2017); Wis JI-Civil 3260.1. The fact that Dr. McMeeking cannot say that his proposed design changes would have "prevented" Ms. Tinlin's injuries does not render his opinions unreliable or otherwise unhelpful to the jury.

Nor have Defendants shown that Dr. McMeeking must state the percentage by which the risk of harm would have been reduced to a mathematical certainty. "Under

Wisconsin law, negligence or defect 'caused' an injury if it was a substantial factor in producing the injury." *Burton v. Am. Cyanamid*, No. 07-CV-0303, 2019 WL 325318, at *2 (E.D. Wis. Jan. 25, 2019); *see Sumnicht v. Toyota Motor Sales, U.S.A.*, 360 N.W.2d 2, 11 (Wis. 1984) ("The long-standing test for cause in Wisconsin is whether the defect was a substantial factor in producing the injury."); *Morgan v. Pa. Gen. Ins.*, 275 N.W.2d 660, 666 (Wis. 1979) ("The test of cause-in-fact is whether the negligence was a 'substantial factor' in producing the injury."); *see also* Wis JI-Civil 1500. Dr. McMeeking's opinion that alternative design features would have "helped to mitigate" the failures that occurred in Ms. Tinlin's filter clearly is relevant to the design defect claims. Doc. 1578-1 at 4.[3]

Defendants contend that Dr. McMeeking's failure to consider Ms. Tinlin's anatomy and medical history precludes him from "quantify[ing] the impact his purported alternative designs would have had on reducing the risk of harm to Ms. Tinlin, or [stating] whether such risk would have been eliminated[.]" Doc. 15075 at 6, 14. Again, Dr. McMeeking is not required to state with certainty that the design changes would have eliminated all risk of harm, or to quantify the reduced risk, in order for his opinions to be reliable and helpful to the jury. Defendants will be free to assert through cross-examination that Dr. McMeeking did not consider Ms. Tinlin's anatomy and medical history.

Defendants note that Dr. McMeeking did not test or analyze caudal anchors, penetration limiters, a two-tiered design, or a chamfered cap. Doc. 15075 at 7-9, 15-17. But this does not preclude the jury from finding that these features are reasonable alternative designs. *See Lynn v. Yamaha Golf-Car Co.*, 894 F. Supp. 2d 606, 629-30 (W.D. Pa. 2012) (a plaintiff "may rely on credible expert testimony that the alternative design could have been practically adopted at the time of sale, even where the expert itself has produced no prototype"). The lack of testing and analysis goes to the weight of Dr. McMeeking's opinions, not their admissibility.

[3] Dr. McMeeking offered similar opinions in the Hyde, Jones, and Booker cases to which Defendants did not object. *See* Docs. 15752-6 at 3, 157524-7 at 4, 15752-8 at 3.

Defendants' reliance on *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017), is misplaced. Doc. 15075 at 15-16. The expert in that case opined that "proven design alternatives existed during the relevant time period that would have *prevented* the [plaintiff's] accident." *Nease*, 848 F.3d at 234 (emphasis added). Dr. McMeeking offers no similar opinion in this case. Rather, he opines that alternative design features – including caudal anchors and penetration limiters – would have helped mitigate the failures that occurred in Ms. Tinlin's filter. Doc. 15078-1 at 4. Defendants do not genuinely dispute that caudal anchors help minimize caudal migration, that penetration limiters help minimize perforation of filter limbs through the IVC wall, or that a chamfered cap helps reduce filter arm fractures. *See* Doc. 15078-1 at 3.[4]

Defendants assert that Dr. McMeeking is not qualified to opine that his proposed "alternative filters" – the Simon Nitinol, Greenfield, and Cook filters – were viable options for Ms. Tinlin. Doc. 15075 at 10-12, 14. But Defendants point to no such opinion in the Tinlin report. Dr. McMeeking mentioned these filters to show that his proposed "design features existed in other IVC filter products already on the market[.]" Doc. 15078-1 at 4.

Defendants note that none of Dr. McMeeking's opinions is a recognized standard or published in peer-reviewed literature. Doc. 15075 at 10, 17. But it does not follow that the opinions are unreliable. Dr. McMeeking is a highly-qualified mechanical engineer and materials scientist. *See* Doc. 10051 at 2. His original report provides a description of the methodology he employed and sets forth objective industry and engineering standards for the design of medical implants. Doc. 7318 at 3-10. The report contains a preliminary description of each Bard filter (*id.* at 10-28) and a more detailed assessment of the design, mechanical behavior, and stress and strain characteristics of the Recovery (*id.* at 28-83).

[4] The other cases cited by Defendants are similarly unhelpful. *See Martinez v. Terex Corp.*, 241 F.R.D. 631, 638 (D. Ariz. 2007) (finding the expert's opinion unreliable where he had never even seen a prototype of this theoretical "total barrier guard system" and sketched a diagram of the system for the first time in his deposition); *Harrison v. Howmedica Osteonics Corp.*, No. 06-0745-PHX-RCB, 2008 WL 906585, at *14 (D. Ariz. Mar. 31, 2008) (the expert offered nothing more than a "bald assertion" that his proposed metallic surface strengthening would have prevented fatigue cracking). In this case, caudal anchors, penetration limiters, and a chamfered cap are not theoretical designs. *See* Doc. 12805 at 6-7.

The assessment includes, among other things, a discussion of Bard's in vivo loading and finite element analyses, its testing protocols, expected filter strains and their effects on reliability, the impact of device geometry and fabrication, and the risk of filter fracture, migration, perforation, and tilt. Dr. McMeeking relies in part on the conclusions reached in his original report to render opinions in the Tinlin case. *See* Doc. 15078-1. The fact that those opinions have not been published or adopted as recognized standards does not render them inadmissible under Rule 702 and *Daubert*.

Dr. McMeeking's alternative design opinions "both rest[] on a reliable foundation and [are] relevant to the task at hand." *Daubert*, 509 U.S. at 597. The Court will deny the motion to exclude with respect to the opinions.

B. Bard's Design Choices.

Dr. McMeeking opines that Bard "made a choice" to design the Recovery without caudal anchors and penetration limiters. Doc. 15078-1 at 3. But he has provided no basis for believing that Bard actually considered and rejected these design features for the Recovery. Doc. 15075-4 at 90-92. Nor can he testify as to Bard's state of mind or intent when designing the Recovery. *Id.*

Plaintiffs assert that Dr. McMeeking's opinions will inform the jury about "the information that Bard had within its internal files at the time it was designing the Recovery and the design feature it ultimately used." Doc. 15752 at 10. But the challenged opinions concern the *choices* Bard made, and opinions about Bard's internal decision-making are not admissible. *See* Doc. 9443 at 8 (precluding expert from expressing opinions on Bard's intent, motives, or state of mind); Doc. 9770 at 6 (excluding expert testimony about Bard's corporate knowledge or intent). The motion to exclude will be granted in this regard.

IT IS ORDERED:

1. Defendants' motion to strike portions of Dr. McMeeking's Tinlin report (Doc. 14016) is **denied**.

2. Defendants' motion to exclude Dr. McMeeking's Tinlin case-specific opinions (Doc. 15075) is **denied in part and granted in part**. The motion is **denied** as to the alternative design opinions and **granted** with respect to Bard's design choices.

Dated this 16th day of April, 2019.

David G. Campbell
Senior United States District Judge

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC
Debra and James Tinlin, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00263-PHX-DGC **ORDER**

Plaintiffs move to exclude certain opinions of Dr. Morris and evidence that Ms. Tinlin's medical care was an intervening cause of injury. Docs. 15077, 16576. The motions are fully briefed. Docs. 15661, 16032, 16890. The parties request oral argument, but it will not aid the Court's decision. *See* Fed. R. Civ. P. 78(b); LRCiv 7.2(f). For reasons stated below, the Court will grant the motion to exclude Dr. Morris's opinions and grant in part and deny in part the motion in limine regarding medical care as an intervening cause of injury.

I. Background.

On May 7, 2005, Dr. Riebe implanted a Bard Recovery filter in Plaintiff Debra Tinlin's inferior vena cava ("IVC"). Ms. Tinlin had multiple chest scans after the implantation, including one taken by Dr. Haller on April 15, 2008.

Ms. Tinlin experienced cardiac tamponade on June 10, 2013. A chest scan showed evidence of two fractured Recovery struts in the right ventricle of her heart. Dr. Roitstein performed emergency surgery to drain a large pericardial effusion. The procedure – a subxiphoid pericardial window – involved removing a small piece of the heart sac and inserting a drainage tube through the incision.

On July 31, 2013, Dr. Kress removed a fractured strut through open heart surgery. A subsequent chest scan revealed multiple fractured struts in the pulmonary arteries. These struts and the filter have not been removed.

II. Motion to Exclude Dr. Morris's Opinions About Drs. Roitstein and Kress.

In his case-specific report, Dr. Morris opines that an interventional radiologist could have drained Ms. Tinlin's pericardial effusion through percutaneous placement of a drainage tube. Doc. 15081-2 at 18, ¶ 6. He claims that this procedure "likely would have been performed more expeditiously, with less morbidity and risk than [Dr. Roitstein's] surgical procedure, using moderate sedation rather than general anesthesia." *Id.*

Dr. Morris further opines that the fractured strut Dr. Kress removed potentially could have been retrieved percutaneously by an interventional radiologist, which "might have precluded open heart surgery, with all of its attendant risks and morbidity, including tracheomalacia and epigastric ventral hernia." *Id.* at 18-19, ¶ 7. Dr. Morris notes that a chest scan taken two days before the surgery revealed no strut in the heart. *Id.* He opines that the failure to perform a chest scan immediately before surgery is significant because "it was possible that neither arm fragment was still located in the heart, and therefore, open heart surgery would have been contraindicated." *Id.* at 19, ¶ 7.

Plaintiffs have filed a motion to exclude these opinions, arguing that Dr. Morris is not qualified to opine on the standard of care for cardiothoracic surgeons and his opinions

are unreliable and would be unhelpful and confusing to the jury. Doc. 15081-1 at 3-4. Defendants make clear that they are not offering Dr. Morris to opine on the standard of care for the surgeries performed by Drs. Roitstein and Kress, or any related breach. Doc. 15661 at 6, 11. Defendants assert that they are merely "exercising [their] right under Wisconsin law to present expert testimony that may 'weaken' Plaintiffs' claim of injuries[.]" *Id.* at 11 (citations omitted).

Under Wisconsin law, "when a tortfeasor causes an injury to another person who then undergoes unnecessary medical treatment of those injuries despite having exercised ordinary care in selecting her doctor, the tortfeasor is responsible for all of that person's damages arising from any mistaken or unnecessary surgery." *Hanson v. Am. Family Mut. Ins.*, 716 N.W.2d 866, 871 (Wis. 2006) (citing *Butzow v. Wausau Mem'l Hosp.*, 187 N.W.2d 349, 351-52 (Wis. 1971)). The rule was first announced in *Selleck v. City of Janesville*, 75 N.W. 975, 976 (Wis. 1898):

> The plaintiff is not held responsible for the errors or mistakes of a physician or surgeon in treating an injury received by a defect[,] providing she exercises ordinary care in procuring the services of such physician. Where one is injured by the negligence of another, . . . if her damages have not been increased by her own subsequent want of ordinary care she will be entitled to recover in consequence of the wrong done, and the full extent of damage, although the physician that she employed omitted to employ the remedies most approved in similar cases, and by reason thereof the damage to the injured party was not diminished as much as it otherwise should have been.

The *Selleck* rule remains good law in Wisconsin. *See Fouse v. Persons*, 259 N.W.2d 92, 95 (Wis. 1977) ("The rule for awarding damages for injuries aggravated by subsequent mistaken medical treatment was established in *Selleck* . . . and has been followed since."); *Paddock v. United States*, No. 16-CV-947, 2018 WL 3696618, at *3 (E.D. Wis. Aug. 3, 2018) (discussing the "long-standing principle set forth in *Selleck*"); *see also* Wis Civil-JI 1710 (citing *Selleck* to support the jury instruction for aggravation of injury because of medical negligence).

Defendants do not dispute that the surgeries performed by Drs. Roitstein and Kress were undertaken to treat injuries Ms. Tinlin sustained from the Recovery arm fragment in her heart. *See* Docs. 15081-2 at 6-7, 16952 at 5. Nor do Defendants present any evidence or argument that Ms. Tinlin was negligent in selecting the doctors to perform the surgeries. Thus, even if the surgeries were unnecessary as Dr. Morris suggests, Plaintiffs still can recover resulting damages under the *Selleck* rule if Defendants are found liable at trial.

As a result, Defendants have not shown that Dr. Morris's opinions about the treatment provided by Drs. Roitstein and Kress are relevant to any issue in the case. The opinions would be unhelpful and confusing to the jury. The Court will grant the motion to exclude the opinions. *See* Fed. Rs. Evid. 401-03.[1]

III. Motion in Limine No. 1: Medical Care as an Intervening Cause of Injury.

Plaintiffs argue that under the *Selleck* rule, Defendants should be precluded from offering Dr. Morris's opinions that an interventional radiologist could have drained Ms. Tinlin's pericardial effusion and retrieved the Recovery arm fragment from her heart through percutaneous procedures less intrusive than heart surgeries. Doc. 16576 at 1-2 & n.1 (citing Doc. 15661 at 2). The Court agrees for reasons stated above, and will grant the motion in limine in this regard.

Plaintiffs argue more broadly that Defendants should be precluded from offering any evidence that Ms. Tinlin's medical care was an intervening cause of her injury. *Id.* at 2. But Plaintiffs identify no specific evidence other than Dr. Morris's opinions discussed above.

Defendants make clear that they intend to present evidence that Dr. Riebe's decision to implant a Recovery in Ms. Tinlin after measuring her IVC diameter at larger than 28 mm constitutes negligence that was an intervening cause of her injuries. Doc. 16890 at 3-4. Defendants also intend to present evidence that the April 15, 2008 chest scan showed

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[1] Given this ruling, the Court need not determine whether the opinions are reliable under Rule 702 and *Daubert*. Nor must the Court decide whether Dr. Morris is qualified to opine on the standard of care for cardiothoracic surgeons given Defendants' avowal that no such opinion will be offered at trial. *See* Doc. 15661 at 6, 11.

foreign metallic bodies in Ms. Tinlin's heart, and Dr. Haller's failure to identify this abnormality prevented Ms. Tinlin's treating physicians from properly evaluating her condition before the Recovery arm fragments became symptomatic and caused her injury five years later. *Id.* at 4. Defendants argue that the *Selleck* rule does not apply because the negligence of Drs. Riebe and Haller preceded Ms. Tinlin's injuries – her cardiac tamponade and pericardial effusion procedure, the open heart surgery to remove a fractured strut, and subsequent medical complications. *Id.*[2]

Defendants also raise this issue in the parties' proposed final pretrial order, asserting that the jury is entitled to consider the negligence of both Dr. Riebe and Dr. Haller, and to allocate a percentage of fault to each of them because their negligence was a cause of Ms. Tinlin's injuries. Doc. 16952 at 18 (citing *Connar v. W. Shore Equip. of Milwaukee, Inc.*, 227 N.W.2d 660, 662 (Wis. 1975) (explaining that "when apportioning negligence, a jury must have the opportunity to consider the negligence of all parties to the transaction")). In response, Plaintiffs reference their motion in limine and contend that under the *Selleck* rule, Defendants are liable for the full amount of damages caused by the aggravation of Ms. Tinlin's injuries. *Id.* at 19; *see also* Doc. 16950 at 45. But Plaintiffs fail to address Defendants' argument that the *Selleck* rule does not apply because the alleged negligence of Drs. Riebe and Haller preceded, rather than aggravated, Ms. Tinlin's injuries.

Plaintiffs have not shown that evidence regarding the medical care provided by Drs. Riebe and Haller should be excluded. The Court will deny the motion in limine in this respect.[3]

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[2] Defendants contend that an asymptomatic filter complication is not an injury. *Id.*

[3] Plaintiffs contend that a directed verdict is proper on this issue because Defendants lack the requisite expert opinion that the alleged negligence of Drs. Riebe and Haller was a cause of Ms. Tinlin's injuries. Doc. 16952 at 19. Plaintiff will be free to raise this argument at the appropriate time during trial. *See* Fed. R. Civ. P. 50.

IT IS ORDERED:

1. Plaintiffs' motion to exclude certain opinions of Dr. Morris (Doc. 15077) is **granted**. Dr. Morris is precluded from opining that the surgeries performed by Drs. Roitstein and Kress were unnecessary. *See* Doc. 15081-2 at 18-19, ¶¶ 6-7.

2. Plaintiffs' motion in limine regarding medical care as an intervening cause of injury (Doc. 16576) is **granted in part and in denied part**. The motion is **granted** regarding the medical care provided by Drs. Roitstein and Kress and **denied** with respect to the care provided by Drs. Riebe and Haller.

Dated this 23rd day of April, 2019.

David G. Campbell
Senior United States District Judge